From: [redacted]
To:
Subject: for foi [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege, ACCESS=Commercial]
Date: Friday, 3 July 2020 6:38:01 AM
Attachments: image001.png
image002.png

From: [redacted]@health.gov.au>
Sent: Wednesday, 26 June 2019 2:37 PM
To: [redacted]@health.gov.au>; [redacted]
[redacted]@health.gov.au>; [redacted]@health.gov.au>
Cc: [redacted]@health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Thanks [redacted]

I have provided the clinical comments to J&J who have now requested a teleconference to discuss these with their clinical area overseas (US). Given the time difference J&J have requested **10am Friday**. If you could please confirm your availability for this that would be lovely ([redacted] if you could also please advise).

[redacted] from J&J indicated that they have a teleconference with Ireland this evening as they have asked similar questions to us. He did however indicate that MedSafe and MHRA have agreed to the retail level action (FDA and other EU regulators still pending).

At this stage I'll be handing this one over to [redacted] (cc'd) as I will be out of the office for the next week from tomorrow. Noting you are out today, if you could please advise your availability to [redacted] upon your return [redacted] will send through the teleconference details from there.

Thanks,
[redacted]

From: [redacted] [mailto [redacted]@health.gov.au]
Sent: Wednesday, 26 June 2019 6:46 AM
Subject: FW: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial] [SEC=OFFICIAL]

Good morning [redacted]

I have completed the WP2 for this recall (it is filed in trim : D19-5680162) and also made some changes to the retail and wholesale letter. [redacted] and [redacted] have reviewed too and are happy with the proposed changes and action (see below email thread). I am in Canberra in a meeting all day today so won't be accessing my emails but [redacted] is in the office if you have any urgent queries. Otherwise I will be back in the office tomorrow.

Kind regards,

[redacted]

Sent with BlackBerry Work
(www.blackberry.com)

From [redacted]@health.gov.au>
Date: Tuesday, 25 Jun 2019, 8:19 pm
To: [redacted]@health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Great work [redacted] can you send them to [redacted] please.

Regards
[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 4:49 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Forgot to say in the last email after you have had a chance to review the retail and wholesale letter can you let me know if you are happy for me to forward them and the WP2 to [redacted]

Thanks,
[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 4:23 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi thanks [redacted]

Yes I've made tracked edits to the retail and wholesale letters but didn't see a specific customer letter?

Retail Letter: D19-5669941
Wholesale Letter: D19-5669942

I don't think [redacted] mentioned a customer letter in [redacted] original email (below).

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 3:58 PM
To: [redacted]

Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Looks good. Did you have to edit the customer letter also?

[redacted]

From: O'Dowd, Teresa
Sent: Tuesday, 25 June 2019 1:02 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

WP2 updated D19-5680162 and [redacted] additional advice added.

Thanks,
[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 12:39 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Awesome thanks
[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 12:37 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

No problem at all [redacted] I'll do that right now and flick you an email once its updated.

Thanks,
[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 12:36 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Update and send to me please... [redacted] ..so if you can update and I will review

Thanks
[redacted]

From: [redacted]

Sent: Tuesday, 25 June 2019 10:42 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

I will update the WP2 with the advice from [redacted] but just wanted to check if you had anything you wanted me to change or add before I update the WP2?

Thanks,
[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 10:39 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Did you take the advice from [redacted] and incorporate?

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 10:38 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hey [redacted]

Just wondering if you had a chance to look at this recall yet or if you have any feedback or advice before I send it back to [redacted]

Thanks alot,
[redacted]

From [redacted]
Sent: Monday, 24 June 2019 5:02 PM
To: Devices Clinical Advice; [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted] and thanks
I share your concerns, noting that acne sufferers could be on relevant medications.
As the company does not intend to return this device to market, they presumably should not object to it being a Class 1 recall instead of Class 2, but [redacted] may be able to advise.

However, misuse by

Also

"wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2retinal exposure guideline of ANSI Z80.36-2016[3]."

Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an

enthusiastic juvenile is possible.

Sponsor will not know which customers have bought the device (sold through chemists with no medical practitioner supervision), so cant do letter to patient customers.
They should do an advert in paper though for patients to return device to the point of sale for a refund.

I note only 30 doses per mask, so if recall now, patients should not be exposed after 1 to 2 months of use so should not be long term risk of access to the device.

Cheers
[redacted]

[redacted]
Devices Clinical Section | Medical Devices Branch
Medical Devices & Product Quality Division
Therapeutic Goods Administration | Health Products Regulation Group
Australian Government Department of Health
T: [redacted] **M:** [redacted] | **E:** [redacted]@health.gov.au
Site: [redacted] | [redacted]
Post: PO Box 100, Canberra ACT 2601, Australia
Mail Drop Point: Symonston #122

[redacted]

From: Devices Clinical Advice
Sent: Monday, 24 June 2019 3:56 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Good afternoon [redacted] and [redacted]

I have completed the WP2 for this recall (it is filed in trim : D19-5680162) and also made some changes to the retail and wholesale letter. Would appreciate your review and to see if you agree with my advice and proposed up-classification to a Class 1 and for a consumer level recall. Also whether you think the amendments to the retail and wholesale letters are appropriate or if there is anything extra we should include. Not sure what other advice I should offer in terms of the proposed recall action (Consumer recall and web statement) or what advice you have on what I have written in the WP2.

[redacted] located an IFU for the device at https://www.neutrogena.com/on/demandware.static/-/Library-Sites-JNJSharedLibrary/default/dwd15e356f/other/IFU%20US%20acne%20mask%2023OCT2018.pdf

Relevant TRIM docs:
TRIM File: E19-581096
WP2: D19-5680162
HHE: D19-5669938

Retail Letter: D19-5669941
Wholesale Letter: D19-5669942
Further info/background: D19-5669933

Thanks in advance for your feedback and advice,

Regards,
[redacted]

From: [redacted]
Sent: Monday, 24 June 2019 1:50 PM
To: Devices Clinical Advice
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hey [redacted]

Yes as per the roster (see attached from our sharepoint site) when you do SAS you do Recalls so if you are covering [redacted] you cover both.

Review the recall and send me your WP2 completed form for us to review.

Cheers
[redacted]

From: Devices Clinical Advice
Sent: Monday, 24 June 2019 1:27 PM
To: [redacted]
Subject: FW: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Just after noticing this come in - not sure whether I'm covering recalls today too with [redacted] being away or just SAS – let me know if you need me to look at the below recall.

Thanks,
[redacted]

From: [redacted]
Sent: Monday, 24 June 2019 12:50 PM
To: Devices Clinical Advice
Subject: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL]

Good Afternoon Device MOs,

We have received a proposed class III retail level recall for the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator. I have assessed this as a class II (per the subject line) as there

is a risk of harm for a subset of the population.

Would appreciate some input, particularly regarding the classification and level of the action. For your reference, I believe I have located an IFU for the device at https://www.neutrogena.com/on/demandware.static/-/Library-Sites-JNJSharedLibrary/default/dwd15e356f/other/IFU%20US%20acne%20mask%2023OCT2018.pdf Notably: page 8 of the HHE states that "foreseeable misuse for the NLTAM currently on the market was defined as: staring directly at the LEDs; or more than 10 min exposure per day" – there are no precautions to this effect in the IFU per the Essential Principles (the closest would be page 12 of the IFU that states "use the mask once daily").

Relevant TRIM docs:
TRIM File: E19-581096
WP2: D19-5680162
HHE: D19-5669938
Retail Letter: D19-5669941
Wholesale Letter: D19-5669942
Further info/background: D19-5669933

I've also sent an email with a few additional questions to J&J (D19-5669942) for them to get back to us in the meantime.

Cheers,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

ASSESSMENT FORM (WP2) – RECALL AND NON RECALL ACTIONS Document 3

RECALLS REFERENCE NUMBER RC-2019-RN-00986-1

Product Name:	NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator Neutrogena Visibly Clear Light Therapy Acne Mask SAP Code: 26202031 Neutrogena Visibly Clear Light Therapy Acne Mask Activator SAP Codes: 26202032 and 26202034 ARTG: 287825 (Johnson & Johnson Pacific Pty Ltd - Red/blue light phototherapy unit)
ARTG Number(s):	287825
Sponsor/Supplier:	Johnson & Johnson Pacific Pty Ltd
Approval Area:	MEDDEV

Problem Description: **Try to cover off:** **1. A high level description of the problem itself;** **2. What is the Overall Risk and associated Hazard for customers and/or users; and** **3. An overarching mitigating statement as to the risk for patients/users. (e.g. no injuries have been reported to date etc)** **Note: The above needs to be covered in 1000 characters max to align with eBS & SARA limitations.**	Johnson & Johnson Pacific are advising that they have received reports of mild, transient visual adverse events from users. For the general population with normal use of the device there is risk of: 1. Distorted colour vision and/or blurred vision due to tearing 2. Temporary loss of hue perception in blue spectrum. 3. Eye pain or irritation 4. Seeing spots or flashes For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a *risk of varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or lead to permanent vision loss.*.
Distribution of affected product:	[redacted]

Hazard Classification[1]	Class II
Hazard description:	hazards relating to 'normal use": 1. Distorted colour vision and/or blurred vision due to tearing 2. Temporary loss of hue perception in blue spectrum. 3. Eye pain or irritation 4. Seeing spots or flashes Hazards relating to 'foreseeable misuse': 1. Temporary loss of hue perception in blue spectrum (colour distortion), ocular discomfort, disability glare, after images and headaches, selective chromatic adaptation (“green vision”).
Likelihood[2] **What are the chances that the issue will occur?**	Possible
Overall Risk[3]	Moderate

Likelihood and Hazard Classification combined – as given in the below table	
Any historically related recall actions for this defect?* **Or for this product for any defect?*** **Or is this product a historic 'Hot Issue' item for any defect?**** *** 3 or more issues in the last 2 years – then detail otherwise answer is no** **** Flagged in TRIM as a Hot Issue or otherwise known to be a Hot Issue.**	No

Proposed Recall Action or Non-Recall Action being taken for product in the Market:	- URGENT MEDICAL DEVICE RECALL Wholesalers: Johnson & Johnson Pacific is advising wholesalers to consolidate affected stock (in warehouse and from retailers) and raise a credit claim. Following processing of the credit claim, Johnson & Johnson Pacific Customer Service will contact facilities to provide a return number and pick up instructions. Retailers: Johnson & Johnson Pacific is advising retailers to contact their wholesaler to arrange credit and return of affected devices. Retailers should direct all consumer returns to the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a credit Consumers: Consumers are advised to contact Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a credit.
Level of action	Consumer level
All end users identifiable?	NO – Distributor will not supply customer list or cannot track batch
What is the Notification Method to end users/patients:	Mail Email/Fax Phone Newspaper advertisement
End user action(s): **(Customer actions)**	Return Product Read correspondence
Is Patient follow up required?	NO
Sponsor Action(s) being taken to fix the problem:	Destroy goods Send to manufacturer Confirm receipt of correspondence
Future Supply:	No future supply

Expected Close	Not expected to take more than 3 months

Out date:	

Does the proposed action meet any of the criteria for Clinical advice from a Medicines, Biologicals or a Devices Medical Officer:	☒ When the clinical implications are unclear in relation to deficiency identified and/or the proposed workaround; AND/OR; ☐ When there is evidence of an actual death or permanent injury in any Jurisdiction, including any International reports; AND/OR; ☐ All Vaccine Recalls, TGA Immunology are also to be informed via emailing Immunobiology@health.gov.au AND/OR; ☐ All Medicines, Biologicals or Medical Devices supplied under the Special Access Scheme (SAS) or Authorised Prescriber (AP) Pathway are to be notified to TGAs Experimental Products Section (EPS) via emailing eps@health.gov.au AND/OR; ☒ Any recall actions that would require a TGA Web Statement. (i.e. Hazard Alerts and/or Consumer Level recalls, Vaccine recalls and other 'one-off' circumstances that have wider health implications or where a Web Statement is determined to be necessary for any reason – please specify this detail in the comments section below); ☒ Yes – Send to Clinical Delegate for advice; OR ☐ No – Recall Coordinator to sign off
Clinical Delegate advice	*I consider the hazard classification to be appropriate. (If NO, provide reasoning and suggested classification in COMMENTS section below)* */ NO* *I consider the proposed action to be appropriate. (If NO, provide reasoning and suggested change/s in COMMENTS section below)* */ NO* *I consider the proposed correspondence to be appropriate. (If NO, provide reasoning in the COMMENTS section below and suggested amendments to the draft customer letter using tracked changes)* */ NO*

	Signed: Dr FirstName LastName <signed electronically> *Date: Insert*
Recall Coordinator Sign off	*Agree with the hazard assessment?* *YES* *Agree with proposed action & correspondence?* *YES* *Signed:* [redacted] *<signed electronically>* *Date: 10/07/2019*

Hazard Classification System:

- **Class I – Most serious *safety-related* -** A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death;

- **Class II – Urgent *safety-related*** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote; and

- **Class III – Lowest risk – *non safety related*** - A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

	Class III [1]	Class II [1]	Class I [1]
Unlikely[2]	**Low[3]**	**Low[3]**	**Moderate[3]**
Possible[2]	**Low[3]**	**Moderate[3]**	**High[3]**
Likely[2]	**Moderate[3]**	**High[3]**	**High[3]**

Likelihood
Risk
Overall Risk

Comments:

The sponsor reports 359 cases of visual/eye signs or symptoms of which they classified seven as serious and 85 cases of neurologic sign or symptoms, where 35 of the consumers attributed these to the light exposure. 3 of these were classed as serious. Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness.

The sponsor has identified that in potentially susceptible populations 'Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss.'

Potentially susceptible populations include persons with these disorders:
• Retinitis Pigmentosa
• Ocular Albinism
• Photosensitive Medication
• Other Hereditary Ocular Disorders.
The sponsor also states that the safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.
Importantly intended users of this device have mild-moderate acne vulgaris. Tetracycline antibiotics e.g. doxycycline and minocycline and the oral contraceptive pill are commonly used to treat moderate acne vulgaris. Oral isotretinoin is used for severe or cystic acne. The aforementioned medications used to treat acne vulgaris are all associated with an increased risk of ocular photosensitivity. There is a very real possibility that many of the users of this device may be taking one or more of the aforementioned photosensitising medications. Importantly, the precautions section of the IFU does not mention ocular photosensitivity or underlying ocular disorders. Therefore, users will be unable to tell from the instructions for use whether it is safe for them to use this device.

Importantly, the instructions for use for this device do not describe any risks of eye injury or vision loss.

For all the aforementioned I advise the Hazard classification be changed to Class 1.

Additionally the sponsor states 'Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population'. The sponsor also states "New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration". The subject device should therefore, be fully recalled at the consumer level as the proposed recall action does not mitigate the risk for consumers who have already purchased this product.

The tracked changes made to both the retail and wholesale letter are also advised. A web statement and consumer level correspondence is also recommended.

Signed: [redacted] *24/06/19 16:00*

25/06/19 12:42
On receipt of additional advice via email (Mon 24/06/19 17:02) from [redacted] the following additional advice should also be considered:

- Misuse by "wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2 retinal exposure guideline of ANSI Z80.36-20163." Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an enthusiastic juvenile is possible. This again highlights the need for a consumer level recall.
- The sponsor will not know which customers have bought the device (sold through chemists with no medical practitioner supervision), so can't do letter to patient customers. **The sponsor should be requested do an advert in paper for patients to return device to the point of sale for a refund.**

[redacted]

Office of Consumer Medical Safety
Johnson & Johnson Family of Consumer Companies

Health Hazard Evaluation

NEUTROGENA Light Therapy Acne Mask
Photobiological Effects of Blue Light

This document is a:
☒ Health Hazard Evaluation (HHE) of Product Released for Use in Market or Research
☐ Health Risk Assessment (HRA) of Product Not Released and within Company Control

Version:	v1.0
Date:	18June 2019
Prepared by:	Office of Consumer Medical Safety
Document Name:	*HHE NTG LightTherapyAcneMask Blue Light Photobio Effect v1.0 FINAL 18-Jun-2019*
Location:	https://jnj.sharepoint.com/teams/skillmansafetyteam/Shared%20Documents/Forms/List.aspx

Product Name	NA and EMEA: Neutrogena Light Therapy Acne Mask AP: Neutrogena Visibly Clear Light Therapy Acne Mask
Panel Code	N/A
Product Code	30035782 (NA, EMEA), 26202033 (AP) / 681012400
Model	Model 31000
Lot/Serial Numbers	All lots in market and within J&J control. UDI (DI:00070501101247)
Marketing Status	Active – Marketed in NA, EMEA, AP

Key: AP – Asia Pacific; EMEA – Europe, Middle East, Africa; NA -North America

1. PROBLEM, DEFINITION AND ANALYSIS

1.1. Summary of the Problem

Phototherapy refers to the use of nonthermal, noninvasive light to achieve a therapeutic outcome and can apply to a variety of light-emitting devices. Recent advances in technology have allowed the use of light emitting diodes (LEDs) for the treatment of medical conditions, such as mild-to-moderate acne vulgaris. The Neutrogena Light Therapy Acne Mask (NLTAM) has an array of blue and red LEDs that deliver light to the skin of the face. The NLTAM has shown efficacy in treating acne breakouts. When used as directed or under foreseeable misuse conditions, there is the potential for the eyes to be exposed to the blue light emitted from the LEDs.

Blue light is widely used in electronic devices such as cell phones and computer monitors and has been considered to be safe when used in compliance with regulatory standards. New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration.

Transient visual adverse events (AE) have been reported by NLTAM users with rare frequency. No pattern of visual disturbances of major clinical concern has been observed and the reporting rates of non-serious transient visual adverse events are rare. However, s11C s11C(1)(b) , given there is no ocular benefit of blue light exposure, the company further evaluated the potential risks of ocular photobiological exposure.

1.2. Product Information

NEUTROGENA® (NTG) Light Therapy Acne Mask is a reusable, non-invasive, non-thermal, non-sterile product commercialized in United States, Canada, Europe and Australia, where it is classified as a Class II medical device; and most countries in Asia Pacific (APAC) where it is classified as a Commodity. The product first launched in the United States in October 2016.

It is indicated to treat mild to moderate facial acne in males and females 12 years or older.

It is a home-use product that emits blue and red light, to target bacteria that cause mild to moderate acne, and to reduce inflammation.

The product kit consists of an acne face mask and a detachable corded activator. Replacement/refill activators are marketed separately. Each activator is designed to provide 30 ten-minute treatment sessions. The user places the mask over the face and presses the power button – holding for 1 second – to initiate treatment. The acne mask has a continuous working time of 10 minutes and shuts off automatically once complete. This product was designed to be used once a day. Continued use after the initial 30 treatment sessions is recommended to see further improvement and this would require a replacement/refill activator.

Each product kit includes an Instructions for Use (IFU) brochure/insert describing the product and its different components, how it works, who should use it, instructions for use, warnings and precautions, risks, storage and care, and troubleshooting. Images of the product package (front and back) are seen below.

Figure 1: Neutrogena Light therapy Acne Mask package

1.3. Analysis

Root cause of the problem (if known)

No root cause investigation was conducted, as this issue did not arise from a product non-conformance.

[redacted] it was determined that the NLTAM design met all the requirements of [redacted] for LED Lighting Products Standards for Eye and Skin Safety, but owing to the positioning and distance of the lights from the eyes, other safety standards [redacted] should be considered. Based on these insights, it was determined that a modified approach to exposure assessment should also be applied to the NLTAM.

[redacted]

As a result of the modified assessment, it was determined that exposure to blue light from the NLTAM can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population. In addition, a theoretical potential risk was identified under normal or foreseeable misuse conditions for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity.

Company's estimate of number of units affected

- *How many units from the affected lots are expected to have or develop the defect?*
  As noted above, there is no product non-conformance, or defect. The below tables provide our best estimate of the number of masks and activators of Neutrogena Light Therapy Acne Mask and Neutrogena Visibly Clear Light Therapy Acne Mask in distribution and under Company control, presented by region/country.

Table 1. Number of MASKS in distribution and under J&J control

Region/Country	**Masks** in distribution (units)	**Masks** under J&J control (units)	Total
EMEA			
Asia Pacific			
North America - United States			
North America - Canada			
Total			

Table 2. Number of ACTIVATORS in distribution and under J&J control

Region/Country	**Activators** in distribution (units)	**Activators** under J&J control (units)	Total
EMEA			
Asia Pacific			
North America - United States			
North America - Canada			
Total			

- *How many units will reach the consumer level, and will the likelihood of harm increase with time? Consider the risk vs. exposure link and if progressive degradation occurs.*
  The numbers of units distributed to market are presented in the tables above.

The effects of exposure when used as directed in normal healthy population will be transient and reversible. In users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders), as well as for users taking medications which could have the potential to enhance ocular photosensitivity, repetitive exposure beyond two doses to the blue light has the potential, in theory, to cause harmful ocular effects. However, it is almost certain that the discomfort caused in this subset of the population would prevent users from subsequent exposure beyond two doses and thereby prevent the ocular harm from occurring (see Section 2. Health Risks and Medical Safety Assessment).

If product failure occurs, does the user easily recognize it?
Not applicable. This issue is not related to a product non-conformance.

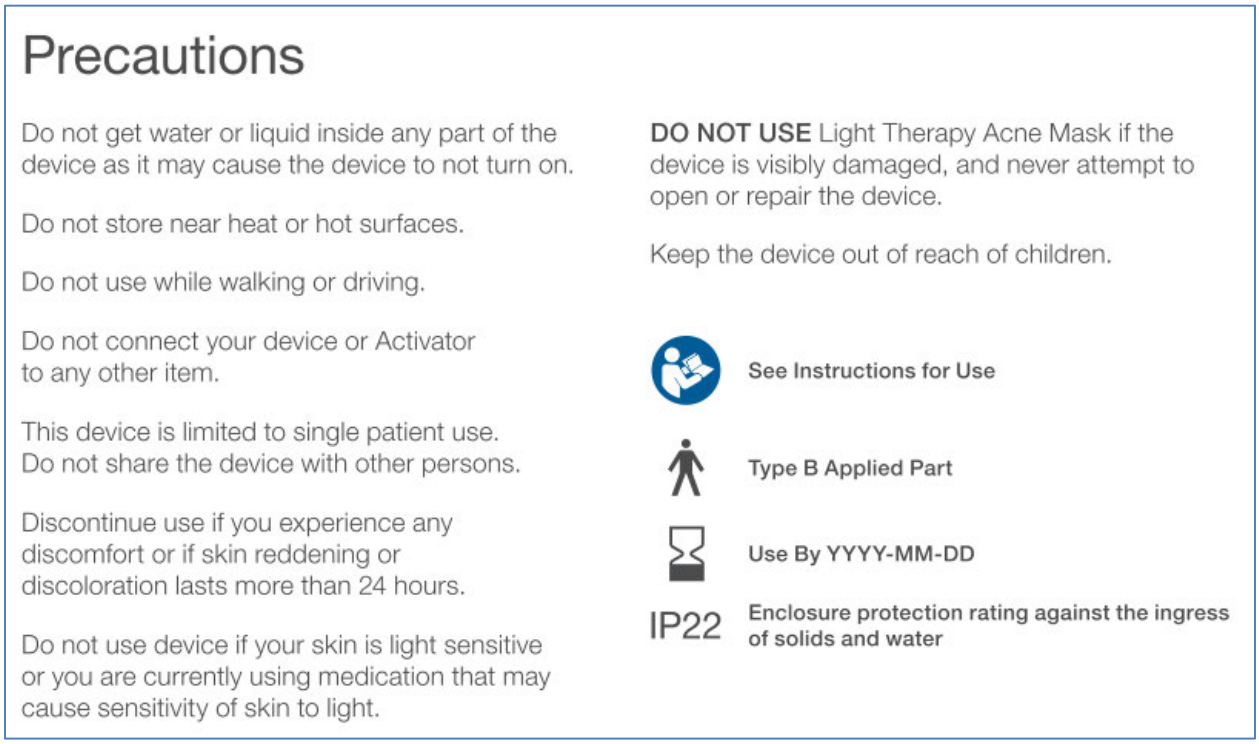
Factors that may contribute to product risk (i.e., product design, manufacturing problems, or user error).
Ocular exposure during use of NLTAM is unintentional. The eye shield included in the mask is not designed to eliminate exposure or fully filter LED light emission.

Factors that might mitigate risk (i.e., product labeling).
At present, the product label/IFU does not contain warnings on potential ocular reactions resulting from product use, but advises consumers to:

- discontinue use if they experience any discomfort, and
- avoid using the device if under treatment with medications that can cause sensitivity to light.

The complete list of precautions for use in the IFU is shown below.

Figure 2. Neutrogena Light Therapy Acne Mask - precautions for use*



** Variation German IFU: "Do not use the device if you are light sensitive or if you are currently taking drugs that could cause a light sensitivity of the skin"*

Does the health consequence have significant public health impact beyond users?
No, there is no health impact beyond the user of the product.

2. HEALTH RISKS AND MEDICAL SAFETY ASSESSMENT

2.1. Exposure Assessment

The company assessed the potential short-term (up to 30 doses) effects and long-term (>1 month up to 5 years) effects of blue light exposure on the retina in association with use of the NLTAM device, in consideration of the intended use, intended users and use environment, and in consideration of foreseeable misuse.

It was determined that the mask design met all the requirements of [redacted] for LED Lighting Products Standards for Eye and Skin Safety, but owing to the positioning and distance of the lights from the eyes, other safety standards [redacted] were considered.

As a result of the modified assessment the investigation determined that blue light exposure from the LED sources in the NLTAM, when used by a subject according to intended-use and consistent with labeling, emit visible light that is well below current guidelines for human

exposure. This conclusion considers all reasonably foreseeable exposure conditions of normal individuals and applies for a single 10-minute (600-s) daily treatment. However, misuse by wearing the mask for two or more sessions in one day would exceed the current 2.2 $J \cdot cm^{-2}$ retinal exposure guideline of ANSI Z80.36-2016[3].

In addition, it was identified that these levels of exposure although appropriate for normal individuals could potentially cause risk to individuals with light-sensitive retinal diseases (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as users taking medications that have the potential to enhance ocular photosensitivity.

The assessment considered the following conditions:

Normal usage: 10 min daily session viewing through the vision slot.

Foreseeable misuse: Foreseeable misuse for the NLTAM currently on the market was defined as:

- Staring directly at the LEDs, or
- More than 10 min exposure/day.

2.2. Risk Characterization Based on Exposure Information

A risk characterization was performed considering the device design (i.e. light power, wavelength, energy, configuration), potential geometries of light exposure, facial features (i.e. eyelids, eyelashes, cheek bones, etc.), aversion responses, photobiological testing conducted, expert review of the current literature and understanding of blue light retinal exposure hazards, and labeling requirements.

The following key factors were included as the basis for the risk evaluation/assessment:

- *Normal Use*: Device used as intended with user looking through viewing slot – 10 min per day
- *Foreseeable Misuse*: Subject stares directly at LEDs or the mask is used more than once per day
- *Acute* was defined as up to 30 doses (maximal use of a single activator), while *Chronic* was defined as daily use from >1 month (30 doses) up to 5 years

This assessment considered exposure to the peripheral retina as per additional testing and indirect illumination of the macula.

[3] American National Standards Institute (ANSI, 2016), *American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments,* ANSI Z80.36-2016, New York, ANSI.

Described below are the potential health consequences, in the normal population and in users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, from use of the NLTAM.

NORMAL POPULATION (Male and Female / 12 years - 25+ years)

a) Normal Use: Device used under normal use conditions (10 min daily treatment time and looking through viewing slot)

1. **Acute:** up to 30 doses
   Temporary (approx. 1 min) adaptation - distorted color vision and/or blurred vision due to tearing.

2. **Chronic:** Device used under normal use conditions (10 min daily treatment time and looking through viewing slot from >1 month (30 doses) up to 5 years)
   Temporary loss of hue perception in blue spectrum (color distortion)

b) Foreseeable Misuse:

1. **User wearing mask more than once daily**
   Temporary loss of hue perception in blue spectrum (color distortion), ocular discomfort, disability glare, after images and headaches, selective chromatic adaptation ("green vision").

2. **User wearing mask - stares directly at LED.**
   Temporary loss of hue perception in blue spectrum (color distortion), ocular discomfort, disability glare, after images and headaches, selective chromatic adaptation ("green vision").

Type of potential exposure considered in normal and foreseeable misuse scenarios: Exposure to peripheral retina and indirect illumination of the macula.

Because of the position of the lower LEDs, the macula is not expected to have direct exposure (indirect illumination of the macula can occur). Duration of exposure is expected to be a fraction of a second as this would likely trigger an aversion response (i.e. blink / close eyes / other).

POTENTIALLY SUSCEPTIBLE POPULATION

No established exposure limits have been identified for blue light in users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders), as well as for users taking medications which could have the potential to enhance

ocular photosensitivity, but the exposure limits would be expected to be lower than in normal subjects.

Potentially susceptible populations include persons with these disorders:

- Retinitis Pigmentosa
- Ocular Albinism
- Photosensitive Medication
- Other Hereditary Ocular Disorders.

The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. The theoretical harms are based on extrapolations of what is known about potential effects of intense light in some of these groups. It is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that may not be directly applicable to the exposure conditions of the NLTAM. Moreover, there is no evidence in post-marketing surveillance of any risk of permanent harm and the incidences of transient light effects are rare. It is almost certain that use will be self-limiting after 1-2 uses in users with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity because of the prolonged and transient effects described, and therefore it is almost certain that no permanent damage would occur from devices that are in the market.

a) Normal Use: device used as directed (10 min daily session looking through the viewing slot)

Up to 2 uses

Initial (up to 2 uses) - Prolonged (hours) and transient color adaptation and/or potential for prolonged and transient loss in hue perception in blue spectrum (color distortion). Intense discomfort to light as well as prolonged but transient adaptation defects – translated into visual acuity and light sensitivity. It is almost certain that this discomfort will prevent subsequent exposure beyond initial use.

More than 2 uses

Small subset / Rare Population - Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss. As noted above it is highly unlikely that repeat exposures beyond two uses would occur in these users as it is almost certain that discomfort caused in this subset of the population would prevent consumers from subsequent exposure beyond 2 doses and thereby prevent the ocular harm from occurring.

b) Foreseeable misuse:

- **User wearing mask -** Stares directly at LED. For this condition the device is used for 10 min daily.

  Initial (up to 2 uses) - Prolonged (hours) and transient color adaptation and/or potential for prolonged and transient loss in hue perception in blue spectrum (color distortion). Intense discomfort to light as well as prolonged but transient adaptation defects – translated into visual acuity and light sensitivity.

  Repeated exposure beyond two uses may potentially cause varying degrees of peripheral retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss. As noted above it is almost certain that these users would not have repeat exposures beyond two uses due to discomfort experienced during initial 1-2 uses.

  Because of the position of the lower LEDs, the macula is not expected to have direct exposure (indirect illumination of the macula can occur). The duration is expected to be a fraction of a second as this would likely trigger an aversion response (i.e. blink / close eyes / other).

- **Device used looking through viewing slot more than 10 min/day:**

  Repeated, consecutive exposure in a single day has the potential to cause varying degrees of retinal damage that can be irreversible and could accelerate peripheral vision impairment or loss. As noted above it is almost certain that these repeat exposures (particularly consecutive, repeat exposures) would not occur in these users since the discomfort in this subset of the population would prevent consumers from subsequent exposure.

2.1.1. Characterization of susceptible population

It is difficult to characterize the population with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity as it encompasses a heterogenous group with varying clinical stages and risks.

The following describes some medical conditions that may place some users at potential risk compared to the normal healthy population.

Retinitis Pigmentosa

Retinitis pigmentosa (RP) is a group of genetic disorders characterized by progressive retinal degeneration and dysfunction, affecting primarily photoreceptor and pigment epithelial function.[4] It may occur alone or as part of a syndrome. A family history of RP is present in approximately 70% of patients. The worldwide prevalence of RP is estimated at 1 in 4000 to 5000. [5]

The most common form of RP presents with symptoms restricted to the eye (ie, non-syndromic RP). Multi-organ involvement is seen in syndromic forms of RP, such as Usher Syndrome, where a patient can present with congenital or early-onset hearing impairment followed by the development of RP.[5]

Ocular symptoms of RP arise from loss of retinal rods and cones. Common manifestations include night blindness and loss of peripheral vision.[6] Visual acuity is variably affected. Other symptoms reported by patients include photopsias (sensations of sparkling lights) and headache.[7] Other ocular abnormalities that may occur with RP are astigmatism, myopia, and changes in visual acuity and color vision.

The clinical presentation of RP is variable, with some patients experiencing visual loss during childhood while others remaining asymptomatic until adulthood. The natural course of the RP is gradual loss of visual field, visual acuity, and electroretinographic activity over time. Due to the narrowing of visual fields, the majority of patients meet criteria for legal blindness by age 40.[8]

Ocular Albinism

Ocular albinism is a genetic condition that reduces the pigmentation of the iris and retina, resulting in severe impairment of visual acuity (loss of sharpness of vision) and problems

[4] Retinitis pigmentosa. A symposium on terminology and methods of examination. Ophthalmology 1983; 90:126.
[5] Syndee Givre, MD, PhDSeema Garg, MD, PhD. Retinitis pigmentosa: Clinical presentation and diagnosis. UpToDate 31-Oct-2017.
[6] Weleber RG, Gregory-Evans K. Retinitis Pigmentosa and Allied Disorders. In: Retina, Ryan SJ (Ed), Elsevier Mosby, 2006. p.395.
[7] Heckenlively JR, Yoser SL, Friedman LH, Oversier JJ. Clinical findings and common symptoms in retinitis pigmentosa. Am J Ophthalmol. 1988;105(5):504.
[8] Hartong DT, Berson EL, Dryja TP. Retinitis pigmentosa. Lancet. 2006;368(9549):1795.

with stereoscopic vision (inability to perceive depth). Unlike other forms of albinism, ocular albinism does not significantly affect the hair/skin color.[9]

The most common type of ocular albinism is ocular albinism type 1 (OA1) or X-linked ocular albinism, resulting from inherited X-linked mutation of GPR143 gene.[10] The prevalence of ocular albinism has been reported to be one male in 20,000 live births. Affected males present with vision abnormalities at birth, which do not worsen with time. Apart from vision loss, patients may present with nystagmus (involuntary eye movement), strabismus (crossed eyes), and sensitivity to light (photophobia). Patients may also present with foveal hypoplasia and abnormalities in the optic nerve.[10]

2.3. Post-marketing Safety Review and Surveillance

NTG Light Therapy Acne Mask Adverse Event (AE) cases received globally from launch through 06 November 2017 were fully processed in the [redacted] Thereafter, the cases received globally were received and continued to be assessed and processed in the [redacted] Both systems were searched, and data was reviewed in aggregate in order to obtain a comprehensive global overview.

[redacted]

A search of the [redacted] database was performed for all cases that met the following criteria:

- Product Family Names (PFN):
  - NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 0443AP
  - NEUTROGENA LIGHT THERAPY ACNE MASK REFILL ACTIVATOR AP 0443AAP
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT ACTIVATOR EU 3LTCACEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT EU 3LTAKIEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE MASK EU 3LTCMAEU
  - NTG LIGHT THERAPY ACNE MASK CAN NTLTAMCA
  - NTG LIGHT THERAPY ACNE MASK USA NTLTAMUS
- MedDRA System Organ Class (SOC): Eye Disorders, Nervous System Disorders
- Product role: Suspect or Interacting
- Region/country: Global

[9] U.S. National Library of Medicine. Ocular albinism. Available at: https://ghr.nlm.nih.gov/condition/ocular-albinism#inheritance

[10] National Organization for Rare Disorders. Rare Disease Database - Ocular Albinism. Available at: https://rarediseases.org/rare-diseases/ocular-albinism/

- Case type: Spontaneous, Solicited, Clinical, or Medical Literature
- Date: cumulative cases received up to 06 November 2017
- Case status: Closed

[redacted]

A search of the [redacted] database was performed for all cases that met the following criteria:

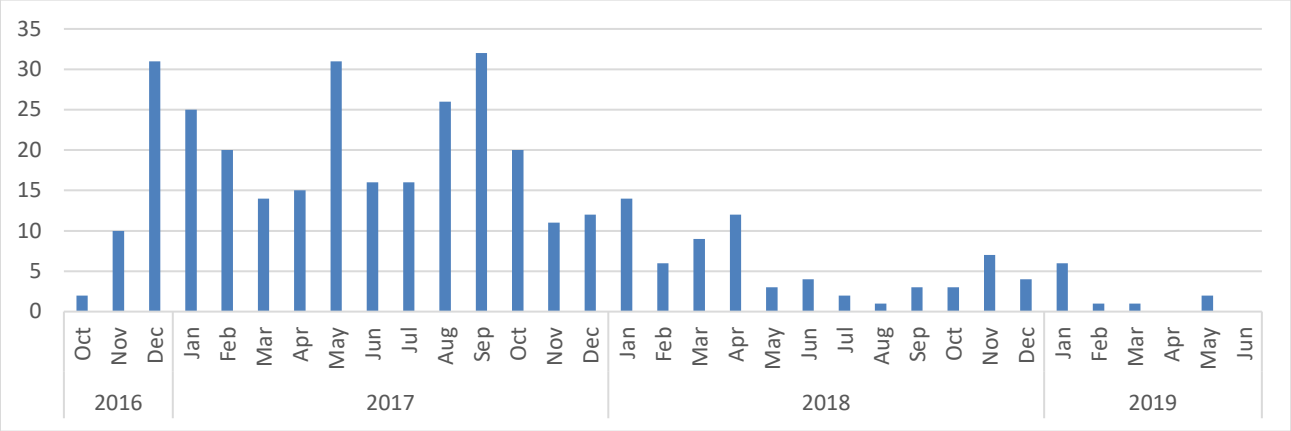
- Product Family Names:
  - NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 0443AP
  - NEUTROGENA LIGHT THERAPY ACNE MASK REFILL ACTIVATOR AP 0443AAP
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT ACTIVATOR EU 3LTCACEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT ACTIVATOR EU 3LTRACEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT EU 3LTAKIEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE MASK EU 3LTCMAEU
  - NTG LIGHT THERAPY ACNE MASK CAN NTLTAMCA
  - NTG LIGHT THERAPY ACNE MASK USA NTLTAMUS
- Case Category Level 3: Neurological Disorder/Disturbance; or Visual Disorder/Disturbance
- Region/country: Global
- Date: Cases received after 06 November 2017 through 13 June 2019

2.3.1. [redacted] and [redacted] database search results for visual/eye signs & symptoms

A total of 359 cases of visual/eye signs or symptoms were extracted from both [redacted] databases received through 13 June 2019. The majority of them were assessed as non-serious (98.05%; 352). Seven were assessed as serious (1.95%).

The graph below represents the monthly distribution of all cases of visual/eye signs or symptoms for the period in scope (Figure 3). The cases and trends are discussed further in the succeeding subsections.

Figure 3: Monthly distribution of all cases of visual/eye signs and symptoms associated with Neutrogena Light Therapy Acne Mask through to 13 June 2019.



Serious cases under Eye Disorder System Organ Class (SOC):

A total of 7 serious cases were identified under Eye Disorders SOC. One case [redacted] pertained to a consumer who experienced sudden temporary vision loss (5 seconds), light sensitivity and headache after using the light therapy mask. This consumer was later diagnosed with idiopathic endocranial hypertension. This case is also included in the section on neurological disorders below.

The remaining 6 cases (see details below) described either retinal injury or visual disturbances (i.e. visual impairment, alleged blindness NOS; refractive error; light sensitivity and vision loss) which were attributed by the consumers, either directly or indirectly, to the effects of the light. However, none of the serious cases were confirmed as causally associated with the light exposure as most of these cases presented concomitant clinical conditions that provided more plausible alternative explanations. Moreover, none of these cases showed evidence of having conditions consistent with the potentially susceptible population and none of the visual disturbances were specifically associated with peripheral retinal damage.

- 2 cases described alleged **retinal injury or detachment**: 1 case [redacted] was received via social media and provided limited information precluding meaningful medical assessment while the other [redacted] was confounded by a history of autoimmune retinal disease which provides a more plausible alternative explanation.
- 1 case [redacted] pertained to alleged **corneal damage** with dryness of the eye and impaired vision, where the treating physician was uncertain about a causal relationship.
- 1 case [redacted] of alleged **blindness** was received via social media and provided limited information precluding meaningful medical assessment.
- 1 case [redacted] described an asymptomatic adolescent who was advised that she required reading glasses during a regular check-up. In this case, the **refractive error** was assessed to most likely be a concomitant condition instead of the effect of 1-month of product use.

- 1 case [redacted] pertained to an adult consumer who used the product despite being advised by a Company representative that this product is not for use by those with light sensitivity. Causal association of product use with **loss of vision and light sensitivity** is confounded by the consumer's medical history (eye surgery 2 years prior to device use and events that have been regularly occurring with every light exposure.)
- 1 case [redacted] pertained to an 18-year-old consumer who experienced **sudden temporary vision loss (5 seconds), light sensitivity and headache** after using the light therapy mask. Best corrective vision at examination was 20/20. Ophthalmological evaluation showed papilledema; macula with no retinal pigment epithelial changes nor retinopathy. The brain CT scan was unremarkable. Final diagnosis was **idiopathic intracranial hypertension.** At follow up patient remained with light sensitivity, headaches and papilledema. Despite a temporal relationship with patient's symptoms, concomitant intracranial hypertension provides a more plausible explanation.

Non-Serious cases under Eye Disorder SOC:

The review of non-serious cases identified ~20% of cases pertaining to users who directly associated the reported events with the lights of the device, with some reporting that the eye shield did not help or that they experienced events even with their eyes closed.

The majority of non-serious cases described reactions that were associated with/may be attributed to light that is perceived as too bright: eye pain, eye discomfort, eye irritation, tearing, blinding, blurring of vision, seeing spots/flashes, and unspecified changes in vision. Forty-percent (40%) of the cases reported changes in vision color, mostly green, while others described other colors, combinations of colors, or unspecified tint in vision.

Events were generally mild and transient. No pattern of adverse events of major clinical concern was identified.

Eye discomfort and blurred vision as well as distorted colors are already outlined as potential risks through light exposure (FM-022680 rev 5) from the NLTAM and are expected to be transient and mild in nature as observed in reviewed cases.

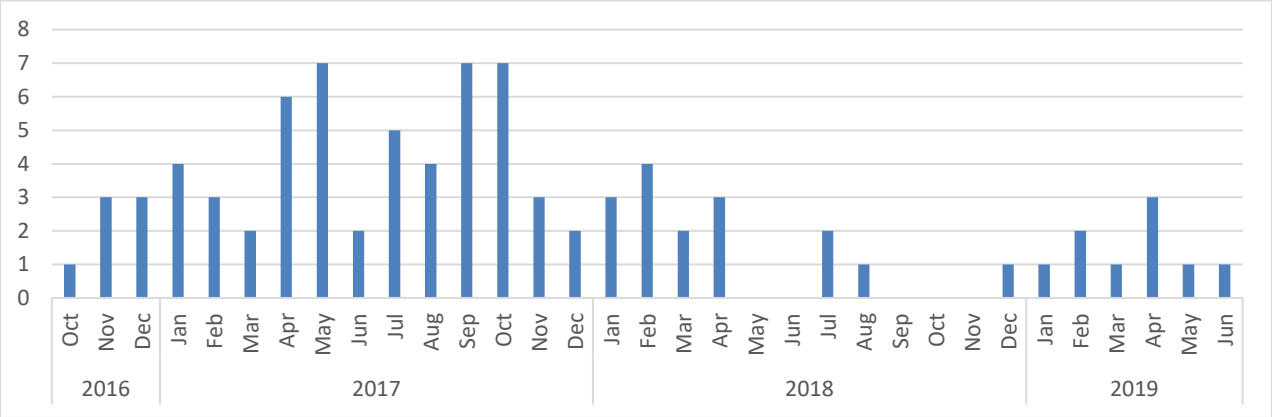
Foreseeable misuse:

A search of all cases in scope of the report identified 2 cases where the consumers used the mask beyond the labeled duration or frequency. The IFU indicates that the product should be used daily, once a day for 10-minutes. One consumer reportedly used the mask 7 times in less than one week and reportedly experienced dry and irritated eyes. Another consumer used the mask twice in a day and reported eye pain and light sensitivity. Both cases were assessed as non-serious.

2.3.2. [redacted] and [redacted] database search results for neurologic disorders

The graph below represents the monthly distribution of all cases of neurologic signs or symptoms for the period in scope (Figure 4). The cases and trends are discussed further in the succeeding subsections.

Figure 4: Monthly distribution of all cases of neurologic signs and symptoms associated with Neutrogena Light Therapy Acne Mask through to 13 June 2019



A total of 85 cases received from October 2016 to June 2019 described neurologic signs or symptoms, where 35 (41.18%) of the consumers attributed these to the light exposure. Overall reporting rate for neurologic signs or symptoms was very rare.

There were 3 (3.53%) cases assessed as serious due to medical significance, reporting optic neuritis (n=1), seizure (n=1), and intracranial hypertension (n=1). None of the reported serious cases are in scope of the blue light potential retinal hazard in this health hazard evaluation and as such are not described further here.

Review of the 80 non-serious cases showed that the majority (66/80; 82.50%) reported headache with or without other associated signs or symptoms such as dizziness, eye pain or blurring of vision. All the events described were clinically mild and transient. Review of cases did not identify a pattern of adverse events of major clinical concern or requiring clinically meaningful interventions.

3. SHIPMENT DATA AND REPORTING RATE (RR)

From October 2016 to May 2019, the product was marketed in 3 regions: North America, Europe/Middle East/Africa, and Asia Pacific. Overall, [redacted] mask kits and [redacted] activator refills were shipped.

The RR was calculated as follows: # of cases per period ÷ Units distributed per period × 1,000,000.

Reporting frequencies are classified according to the CIOMS Working Group[11].

Very common	≥ 1/10	(≥ 100,000 per million units sold)
Common	≥ 1/100 and <1/10	(>10,000 and < 100,000 per million units
Uncommon	≥ 1/1000 and <1/100	(≥ 1,000 and < 10,000 per million units
Rare	≥ 1/10000 and <1/1000	(≥ 100 and < 1,000 per million units sold)
Very Rare	<1/10000	(< 100 per million units sold)
Not known	**(cannot be estimated from the available data)**	

The table below shows the estimated number of units shipped for each region and globally for the Neutrogena Light Therapy Acne Mask and Neutrogena Light Therapy Acne Mask Refill Activator (Table 3).

Table 3: Regional and global shipment data for Neutrogena Light Therapy Acne Mask and Neutrogena Light Therapy Acne Mask Refill Activators from October 2016 to May 2019.

Region	Number of MASK KIT units shipped	Number of ACTIVATOR units shipped
United States	[redacted]	
Canada		
Europe, Middle East, Africa (EMEA)		
Asia Pacific		
Global		

For the purpose of this report, the reporting rate calculations take into consideration that adverse events are mostly reported in relation to the mask. In fact, there were only 2 cases (1 report of headache, 1 report of tearing) reported for the activator. For this reason, only the shipment data for the mask was used in the calculation of reporting rates. [NOTE: For pragmatic reasons, the 2 cases reported for the activator were included in the case count used to calculate the reporting rate.]

The table below shows the reporting rates and corresponding CIOMS classification for each region and globally, for cases of eye reactions and neurological disorders associated with Neutrogena Light Therapy Acne Mask (Table 4). The reporting rates for each region as well as for that for the global portfolio were classified as Rare for eye reactions and Very rare to Rare for neurological events.

[11] Guidelines for Preparing Core Clinical Safety Information on Drugs - Report of CIOMS Working Group III. Geneva, WHO, 1995 (Chapter 5, Good Safety Information Practices).

Table 4: Regional and global reporting rates for eye and neurologic cases (exclusively) associated with Neutrogena Light Therapy Acne Mask from October 2016 to May 2019.

Region	Reporting rate for eye reactions (per million units shipped)	CIOMS Classification	Reporting rate for neurologic disorders (per million units shipped)	CIOMS Classification
United States	185.07	Rare	37.91	Very rare
Canada	255.20	Rare	116.00	Rare
Europe, Middle East, Africa (EMEA)	298.11	Rare	79.50	Very rare
Asia Pacific	356.14	Rare	89.04	Very rare
Global	210.24	Rare	48.02	Very rare

4. CONCLUSION

Available data, additional testing, extrapolations using other light sources and expert opinion informed our risk assessment which defined acute and chronic worst-case scenarios including intended use in the normal population and those with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity, and with foreseeable misuse.

Intended Use in the Normal Population

When used as directed, the Neutrogena Light Therapy Acne Mask meets Health Authorities' requirements for normal acute use in a healthy normal population outlined by [redacted] for LED Lighting Products Standards for Eye and Skin Safety.

Post-marketing data suggest that some users in the normal population develop mild reversible and transient adverse effects (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in color vision). No pattern of major clinical concern was identified for these events. Moreover, no serious adverse events deemed causally related to the mask were identified.

Foreseeable Misuse in the Normal Population

[redacted] it was determined that the mask design met all the requirements of [redacted] for LED Lighting Products Standards for Eye and Skin Safety, but owing to the positioning and distance of the lights from the eyes, other safety standards [redacted] were considered. Based upon these insights it was determined that a modified approach to exposure assessment should also

be applied to the NLTAM. As a result of the modified assessment our investigation determined that exposure to blue light from the NLTAM can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in normal populations.

Two specific foreseeable misuse conditions were evaluated: 1) two or more consecutive treatments 10 min each in a single day while the user is looking through the eye slot, and 2) intentional fixation of gaze on the LEDs during a single 10 min treatment. In both of these situations there is the risk that the peripheral retina could be exposed to more than the calculated daily limit of blue light. Potential harms of this misuse in the normal population include temporary loss of hue perception in the blue spectrum (color distortion) which is expected to be minor in severity. It should be noted that intentional fixation on the LEDs would be expected to be self- limiting due to the brightness of the lights and the normal aversion response and importantly that retinal exposure in this situation would be expected to be well outside the area of central vision and not expected to affect the macula.

Post-marketing data suggest that some users in the normal population may use the NLTAM more often than once daily, but no serious ocular effects were reported in association with this misuse.

Intended Use OR Foreseeable Misuse in those with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity

The safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.

It is predicted that users and misusers in this population would almost certainly develop intense light sensitivity and aversive symptoms (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in color vision, abnormal visual acuity) with any use of the NLTAM, making further use self-limiting.

Should they continue to use the mask in the presence of aversive symptoms, there is a theoretical risk in a very small subset that varying degrees of peripheral retinal damage could occur and that for some this injury could be irreversible and accelerate peripheral vision impairment or loss. As mentioned above, this potential risk of permanent retinal injury in this population is mitigated by the assessment that it is almost certain that initial use of the mask will be self-limiting due to the aversive signs and symptoms and therefore it is highly unlikely that any permanent damage would occur from use of masks that are in the market.

There are no reports in the company's safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users.

CONTRIBUTORS:

[redacted]

SIGNATURES

AUTHOR

I have reviewed this report and confirm that, to the best of my knowledge, it accurately describes the data available to date:

[redacted] Date

[redacted]

Office of Consumer Medical Safety

APPROVER

I have read this report and, based on the data as presented, agree with the conclusions drawn:

[redacted] Date

[redacted]

Office of Consumer Medical Safety

Annex 1: Framework for Assessment of Severity and Probability of the Adverse Health Consequences

Assess the Probability that Use of, or Exposure to, Product under Recall evaluation will Cause Adverse Health Consequences

	Serious Adverse Health Consequences		Medically Reversible or Transient Adverse Health Consequences	
	Overall Population Using Device	**Population at Greatest Risk**	**Overall Population Using Device**	**Population at Greatest Risk**
Very Common[1] (Every Time[2])	☐	☐	☐	☒[3]
Common[1] (Frequent)	☐	☐	☐	☐
Uncommon[1] (Infrequent)	☐	☐	☐	☐
Rare[1] (Reasonable Probability that Use will Cause[2])	☐	☐	☒[4]	☐
Very Rare[1]	☐	☐	☐	☐
Remote (Remote Probability that Use will Cause[2])	☐	☐	☐	☐
Improbable (Not Likely that Use will Cause Any Adverse Events[2])	☒	☒[5]	☐	☐

[1] CIOMS Working Group III [2] FDA CDRH HHE/HRA Form

[3] These are theoretical adverse events for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, and are based on extrapolations of what is known about the potential effects of intense light in this population. There are no reports in the company's safety database associated with the NLTAM that identify individuals with these underlying ocular disorders.

[4] **Based on post-marketing safety data**

[5] This theoretical risk of permanent retinal injury is mitigated by the assessment that it is almost certain that initial use of the mask will be self-limiting due to aversive signs and symptoms and therefore it is extremely unlikely that any permanent damage would occur from use of masks that are in the market. There are no reports in the company's safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users

References

1. Guidelines for Preparing Core Clinical Safety Information on Drugs - Report of CIOMS Working Group III. Geneva, WHO, 1995 (Chapter 5, Good Safety Information Practices).

2. FDA US Food and Drug Administration: CITE: 21CFR7.41

Johnson & Johnson Pacific

DRAFT LETTER TO RETAIL STORES

URGENT MEDICAL DEVICE RECALL

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

Date: 21 June 2019

Dear Retailer,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a **consumer level**.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment; consumers can continue to safely use the Spot Treatment as directed.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Reason for consumer level recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient. For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a risk of permanent eye injury or vision loss.

Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population. In addition, a theoretical potential risk was identified under normal or foreseeable misuse conditions for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity. For this reason all affected devices are being recalled.

Consumers should be advised to discontinue use of the subject device and if they have questions or concerns, or if they would like to return the product and the activator, they are encouraged to call our Johnson & Johnson Pacific Consumer Care Centre on 0800 442 582.

If a consumer reports an adverse experience with the product to you directly, please contact our Johnson & Johnson Pacific Consumer Care Centre immediately on 0800 442 582 so that we can investigate fully.

Actions to be taken:

We understand that you have received one or more of the affected devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Complete the Recall Acknowledgement Form (attached) whether you have stock or not;
- Return the acknowledgement form to your wholesaler;
- Contact your wholesaler to arrange a credit and to organise the return of all affected devices.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products. If you have any other questions, please don't hesitate to contact the [XXX].

Yours sincerely

[redacted]
Johnson & Johnson Pacific

Johnson & Johnson Pacific

DRAFT LETTER TO WHOLESALERS

URGENT MEDICAL DEVICE RECALL

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

Date: 21 June 2019

Dear [customer name],

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a **consumer level**.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment; consumers can continue to safely use the Spot Treatment as directed.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient. For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a risk of permanent eye injury or vision loss.

Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population. In addition, a theoretical potential risk was identified under normal or foreseeable misuse conditions for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity. For this reason all affected devices are being recalled.

Consumers should be advised to discontinue use of the subject device and if they have questions or concerns, or if they would like to return the product and the activator, they are encouraged to call our Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348.

If a consumer reports an adverse experience with the product to you directly, please contact our Johnson & Johnson Pacific Consumer Care Centre immediately on 1800 789 348 so that we can investigate fully.

Actions to be taken:

Our records show that you have received one or more of the affected devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Complete the **Recall Acknowledgement Form** (attached) whether you have affected medical devices or not and return the form to [redacted]**@its.jnj.com**;
- If the affected medical devices have been forwarded to a retail store, contact that retailer with the attached **Letter to Retailers** and the **Recall Acknowledgement Form**, which they need to fill in and return to you, whether they have affected medical devices or not;
- Before you raise a credit claim, please ensure you have collected all acknowledgement forms and affected devices from your retailers;

- Raise a credit claim in your system and email the claim and the consolidated Acknowledgement Forms to [redacted] at [redacted]**@its.jnj.com;**
- Once the claim has been processed, Johnson & Johnson Pacific Customer Service will contact you to provide your return number and pick up instructions.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products. If you have any other questions, please don't hesitate to contact your business manager.

Yours sincerely

[redacted]
Johnson & Johnson Pacific

From:	[redacted] CONAU]
To:	Recalls
Cc:	[redacted] [JJPAU] [redacted] [JJPAU]
Subject:	Attention [redacted]- Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=No Protective Marking]
Date:	Friday, 21 June 2019 3:55:09 PM
Attachments:	TGA ackowledgment form.docx ARTG entry.pdf HHE NTG LightTherapyAcneMask Blue Light Photobio Effect v1.0 FINAL 18-Jun-2019.pdf List of wholesalers AU.xls Neutrogena Retail Letter 210619.docx Neutrogena Wholesale Letter 210619.docx
Importance:	High

Dear [redacted]

Thank you for the phone conversation yesterday afternoon regarding our NEUTROGENA® Visibly® Clear Light Therapy Acne Mask and activator that Johnson & Johnson Pacific (JJP) would like to conduct a voluntary Class III recall from wholesalers and retailers.

Background information

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask on the eye. Out of an abundance of caution, we have made the voluntary decision to recall the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator at the wholesale and retail levels. We have initiated a global stop-ship on this product and the activator.

Description of device and its intended application

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of Red and Blue light via light-emitting diodes (LEDs), and weighs less than 400g.

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator is offered separately to increase the number of doses available from the Neutrogena® Visibly Clear® Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries**.**

Description and justification of the action

Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask are rare, generally mild and transient.

- For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury (further details are described in the Health Hazard Evaluation attached).
- It is predicted that users and misusers in this population would almost certainly develop intense light sensitivity and aversive symptoms (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in colour vision, abnormal visual acuity) with any use of the Mask, making further use self-limiting.
- The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is safe for use by the general population when used as directed.

Corrective action

Corrective action is not applicable as this model of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator will be discontinued globally for commercial reasons.

The following documentation is attached for your reference:

- ARTG entry
- HHE
- DRAFT customer (wholesaler), retailer letters and acknowledgment form
- Customer list – as per our phone conversation we have included the full list of wholesalers. Retailer information is difficult to obtain as it is owned by the wholesalers

We look forward to hearing from you on this matter. Please note [redacted] will be the key contact. Please feel free to reach out to myself or my manager [redacted] [redacted]@ITS.JNJ.com) with any questions.

Kind regards,

[redacted]
[redacted] – Asia Pacific Beauty
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

[redacted]
[redacted] – Asia Pacific Beauty
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

Record Summary

287825 Johnson & Johnson Pacific Pty Ltd - Red/blue light phototherapy unit

Sponsor	Johnson & Johnson Pacific Pty Ltd
Therapeutic Type	Medical Device
Product Category	Included Class IIa
ARTG Start date	12/04/2017
Postal Address	Locked Bag 5, BROADWAY, NSW, 2007 Australia
Billing Address	Locked Bag 5, BROADWAY, NSW, 2007 Australia

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Certificate number(s)
Johnson & Johnson GmbH	Johnson & Johnson Platz 2 , Neuss, 41470 Germany	DV-2017-MC-00391-1

Products

1.Red/blue light phototherapy unit

Product Type	Single Device Product	**Status**	Current
		Effective date	12/04/2017

GMDN	62116 Red/blue light phototherapy unit
Functional description	Not included on record
Intended purpose	An assembly of battery-powered devices intended to emit both red and blue light for the treatment of a facial skin condition by the patient in the home.
Variant information	

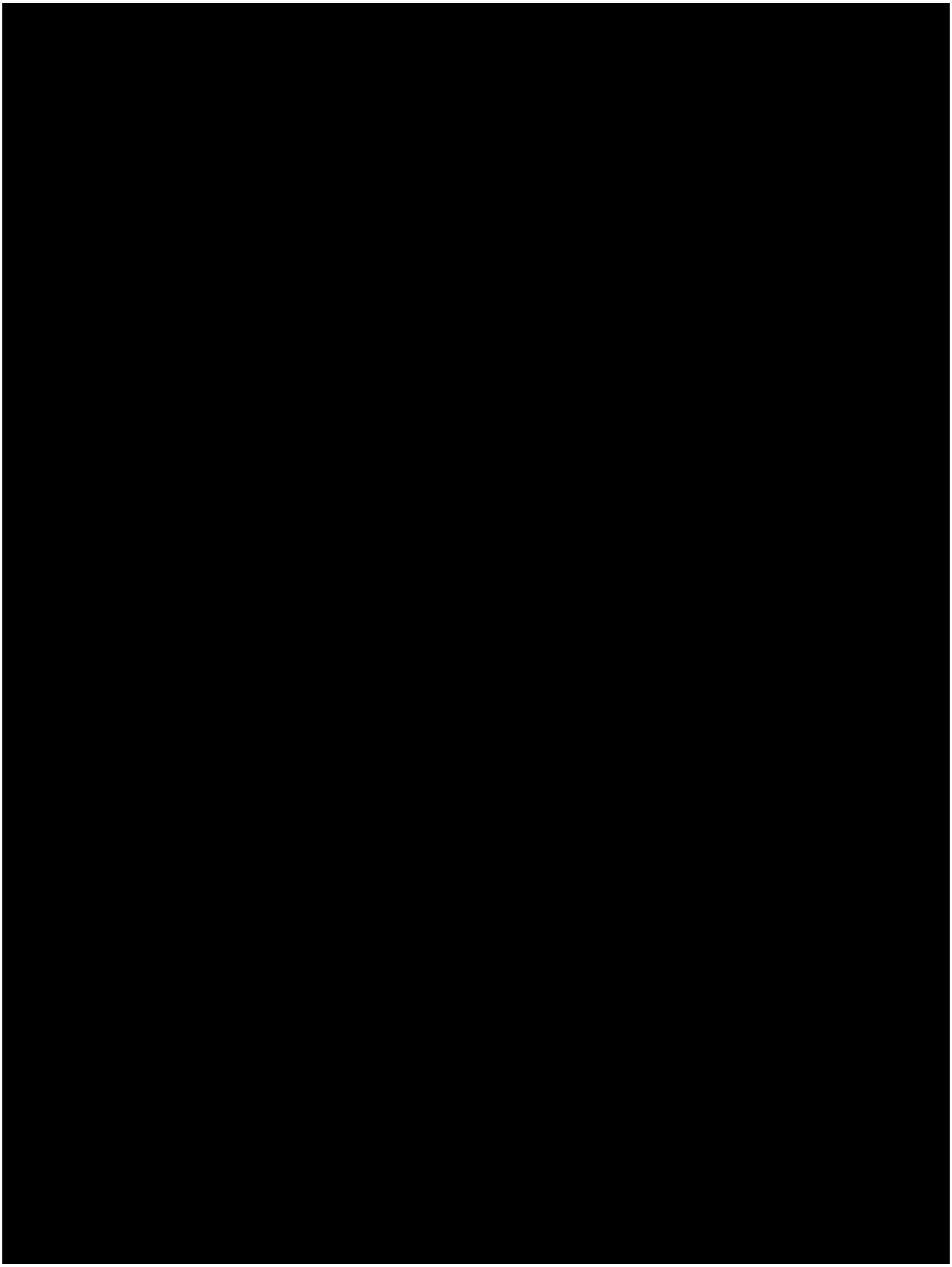
Device Information

Record Summary

Specific Conditions

No Specific Conditions included on Record

Record Summary



Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

MEDICAL DEVICE RECALL

TGA Recall Reference Number: [Number]

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask

and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator

AFFECTED DEVICES:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

On behalf of this organisation I acknowledge receipt of the Medical Device Recall notice date [insert date of notice] relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	Batch/Lot/Date	Quantity of stock received	Quantity of unused stock subject to recall (currently in quarantine)
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Name	[redacted]
Position	[redacted]
Organisation	Johnson & Johnson Pacific
Address	45 Jones Street, Ultimo NSW 2007
Email	[redacted]@its.jnj.com
Subject of email	Neutrogena Visibly Clear Light Therapy Acne Mask and Activator [do we need a number?]
Telephone no.	1800 638 047 (press '2')

NEUTROGENA

Light Therapy Acne Mask

Instructions for Use

Neutrogena Light Therapy Acne Mask

Document 3

Experience a revolutionary device inspired by dermatologist treatments that brings acne light therapy into your home. Therapeutic blue and red lights treat acne by targeting the bacteria that cause acne.

Use Light Therapy Acne Mask once a day.

Light Therapy Acne Mask will turn off automatically at the end of each 10 minute treatment and will last for 30 treatment-sessions.

Continue to use Light Therapy Acne Mask after your 30 treatment-sessions end to see further improvement in your skin.

Welcome to a new you.

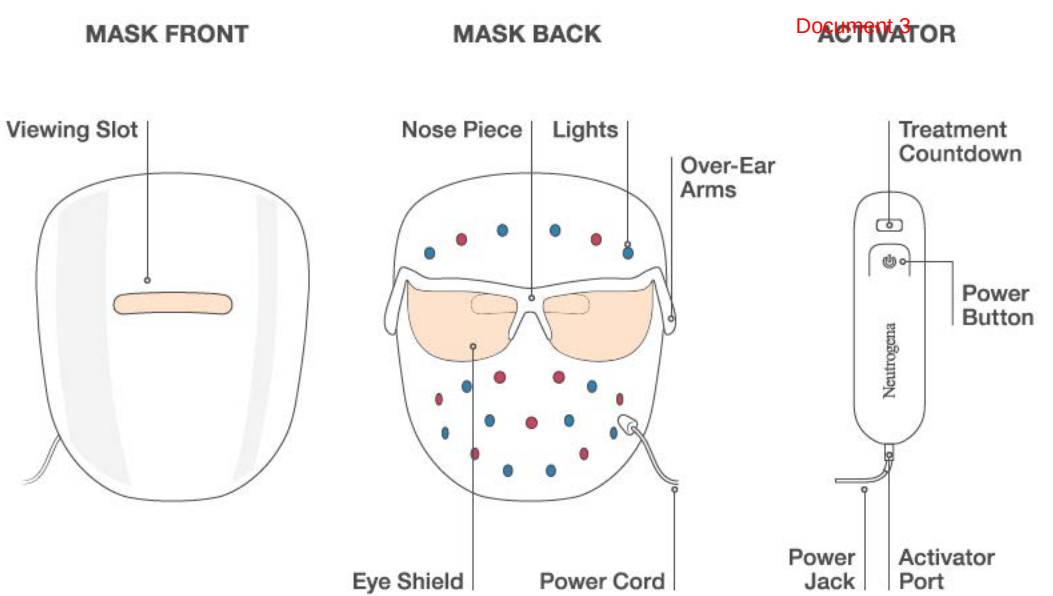
www.neutrogena.com

Table of contents

Document 3

Getting to know the Light Therapy Acne Mask

Document 3


MASK FRONT
MASK BACK
ACTIVATOR
Viewing Slot
Nose Piece
Lights
Over-Ear Arms
Eye Shield
Power Cord
Treatment Countdown
Power Button
Neutrogena
Power Jack
Activator Port

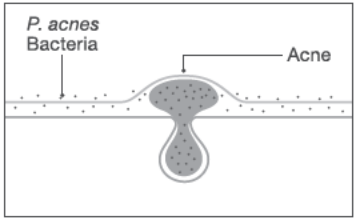
How Light Therapy Acne Mask works

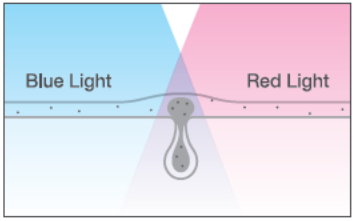
Document 3

Acne starts with the buildup of oil under the skin which causes a type of bacteria called *P. acnes* to multiply. Pores get blocked with this bacteria, excess oil, and dead skin cells. The result is an acne breakout.

Document 3

Blue and red light therapy treats acne by targeting the bacteria in the skin that causes acne breakouts. The light gently penetrates the skin to reduce the bacteria. When you reduce bacteria, you reduce the appearance of acne breakouts[1,2,3]. Light Therapy Acne Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.





Footnotes:

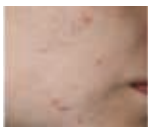
1. Goldberg, D. and Russell, B. Combination Blue (415 nm) and Red (633 nm) LED Phototherapy in the Treatment of Mild to Severe Acne Vulgaris. *Journal of Cosmetic and Laser Therapy.* 2006; 8: 71-75
2. Lee, S., You, C. and Park, M. Blue and Red Light Combination LED Phototherapy for Acne Vulgaris in Patients with Skin Phototype IV. *Lasers in Surgery and Medicine.* 2007. 39:180-188
3. Ashkenazi, H., et al. Eradication of *Propionibacterium acnes* by its Endogenic Porphyrins After Illumination with High Intensity Blue Light. ***FEMS Immunology and Medical Microbiology.*** 2003; 35:17-24

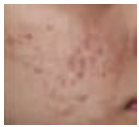
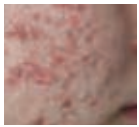
Who should use Light Therapy Acne Mask

Document 3

Use this chart[4] to help determine if Light Therapy Acne Mask is right for you.

Indications for Use: Light Therapy Acne Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

Acne Type	Should You Use Light Therapy Acne Mask	Description	Example
Clear Skin	No	No Acne	
Mild Acne	Yes	Up to some blackheads and whiteheads, a few pimples and pustule, no nodules	

Acne Type	Should You Use Light Therapy Acne Mask	Description	Example
Moderate Acne	Yes	Up to many blackheads and whiteheads, some pimples and pustules, only a few small nodules.	
Severe Acne	No. This product is not recommended for severe acne as the benefits have not been established.	Up to many blackheads, whiteheads, pimples and pustules, some nodules.	

See glossary for definitions.

Footnotes:

4. Acne assessment criteria are based off of the FDA Proposed Acne Scale for Baseline Assessment. "US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). Guidance for Industry; Acne Vulgaris: Developing Drugs for Treatment (2005)."

Warnings

Document 3

DO NOT USE Light Therapy Acne Mask if you are pregnant, may be pregnant, or nursing as the risks are unknown and have not been established.

Precautions

Document 3

Do not get water or liquid inside any part of the device as it may cause the device to not turn on.

Do not store near heat or hot surfaces.

Do not use while walking or driving.

Do not connect your device or Activator to any other item.

This device is limited to single patient use. Do not share the device with other persons.

Discontinue use if you experience any discomfort or if skin reddening or discoloration lasts more than 24 hours.

Do not use device if your skin is light sensitive or you are currently using medication that may cause sensitivity of skin to light.

DO NOT USE Light Therapy Acne Mask if the device is visibly damaged, and never attempt to open or repair the device.

Keep the device out of reach of children.

See Instructions for Use

Type B Applied Part

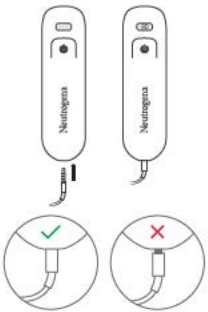
Use By YYYY-MM-DD

IP22 **Enclosure protection rating against the ingress of solids and water**

How to use Light Therapy Acne Mask

Document 3

1. Connect the Light Therapy Acne Mask to the Activator. Make sure the plug is fully inserted into the Activator, with no silver metal visible. Your Mask will last for 30 treatment-sessions. Each treatment-session lasts for 10 minutes. Use the Mask once daily.



2. Wash and dry your face prior to each treatment-session to remove oil and makeup.

3. Open the over-ear arms and put on Light Therapy Acne Mask like you would a pair of glasses.

For the most consistent results with Light Therapy Acne Mask, use it to complement your regular skin care routine and do not skip sessions.

Document 3

4. Press and hold the power button for 1-3 seconds to begin your treatment until your mask powers on. Relax with the Light Therapy Acne Mask for 10 minutes.

5. Light Therapy Acne Mask will turn off automatically after 10 minutes. If you need to turn Light Therapy Acne Mask off during the treatment, press and hold the power button for 1 second. Note that doing so will decrease the remaining number of sessions by one.

6. After each treatment-session, the counter will show how many treatment-sessions remain. Once the counter reaches 0, disconnect and discard the Activator. Keep the Mask and purchase a new Activator for more treatment-sessions.

Risks

Document 3

Event: Correct Use: 35 of 35 subjects made no error using the device.

Hazard	How Often Subjects Had the Hazard	Harm	How Often This Hazard Harmed Them
No known hazard from correct use of the Light Therapy Acne Mask.	Not applicable	Not applicable	Not applicable

Event: Correct Use: 0 of 35 subjects made at least one error using device**

Hazard	How Often Subjects Had the Hazard	Harm	How Often This Hazard Harmed Them
Device was shared with another person.	0 of 35 subjects	Possible cross contamination.	0 of 35 subjects
Did not remember or comprehend instructions and warnings about use while pregnant or nursing.	0 of 35 subjects	Unknown, unreported, unobserved.	0 of 35 subjects

Risks

Document 3

Hazard	How Often Subjects Had the Hazard	Harm	How Often This Hazard Harmed Them
Did not remember or understand instructions and warnings	0 of 35 subjects	Unknown, unreported, unobserved.	0 of 35 subjects
Water or liquid got inside the device	0 of 35 subjects	Device may not turn on.	0 of 35 subjects

*Correct use: Doing all things and steps exactly like the user manual directs.

**Incorrect use: Failing to follow the instructions for use given in the manual provided with Light Therapy Acne Mask device. Reasons for incorrect use include, but are not limited to, not understanding information and /or choosing to not follow instructions one does understand.

Note: The data provided in the above Risk charts was obtained from the Usability Study conducted in May 2013.

This data is representative of the potential risks that occur. Only the known risks are listed. However, the device is a minimal risk device when used in accordance with the Instructions for Use provided in the manual accompanying the device. Although the use of light therapy, such as used with the Light Therapy Acne Mask acne device has been shown to be safe, there may be unforeseeable risks that have not been identified at this time. The possibility of risks that may occur with the use of light therapy include:

1. Mild reddening of the skin
2. Mild tingling sensations

Storage & Care

Document 3

Cleaning
Clean the eye shield frame or outside of Light Therapy Acne Mask whenever it appears dirty. Moisten a soft cloth with water or isopropyl alcohol and lightly wipe down the device. Do not get water or liquid inside any part of the device.

Maintenance
Light Therapy Acne Mask does not need regular or special maintenance. No modification of this equipment is allowed.

Operating Conditions
5 °C to 35 °C; 15%-75% Relative Humidity, non-condensing; Atmospheric Pressure: 700-1060 hPa

Transport and Storage Between Uses Conditions
-25 °C to 45 °C; up to 75% Relative Humidity, non-condensing

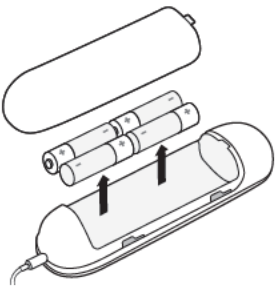
For best performance of the device, store in a cool dry place, but do not refrigerate. Do not store near heat or hot surfaces. For long-term storage, unplug the Mask from the Activator.

Travel
If traveling with Light Therapy Acne Mask, pack the device in its original packaging to prevent damage.

Life of the Activator
Activator is designed to work for 30 treatment-sessions. Dispose of properly after session counter reaches 0 and replace with a new Activator refill to re-activate the Mask.

Shelf Life
For the Activator, refer to the expiration date on the back panel of the Activator.
For the Mask, refer to the expiration date on the eyeglass arm.

Disposal (4 AA batteries included)
When you have finished your last treatment session, please remove the batteries in the Activator. Please follow your local regulations for proper disposal of battery operated devices. Dispose of batteries by removing the back panel of the Activator.



Troubleshooting

Document 3

Problem	Possible Cause	Action Required
Unit will not function	Mask cord is not fully connected to Activator and silver plug is showing	Make sure Mask is fully plugged in to Activator, with no metal visible
	'On' power button was not pressed and held for 1-3 seconds until mask powers on	'On' button should be pressed and held for 1-3 seconds until the Mask powers on and is located on the Activator
	All 30 treatment-sessions have been used	See counter for remaining sessions and dispose of the device accordingly Dispose and purchase a new refill Activator
	Mask or Activator are used past the Expiration Date	Dispose and purchase a new Activator
Mask does not fit	Over-ear arms have not been extended properly	Use over-ear arms and nosepiece to position the Mask for a comfortable fit
Light flickers during session	Battery power intermittent or power jack of the Mask is not fully plugged into the Activator port.	Check that the power cord is in good condition and that the Mask is fully plugged in to the Activator, with no metal visible. If the problem persists, contact 800-582-4048. Outside US, dial collect 215-273-8755

If you have any unresolved problems, 800-582-4048; Outside US, dial collect 215-273-8755. www.neutrogena.com

Glossary

Document 3

Bacteria
Propionibacterium acnes (*P. acnes*) that causes acne breakouts. It lives on oil secreted by the skin.

Blackhead
A small bump on the skin with a black center, not inflamed.

Inflamed
Red and sensitive to the touch.

Nodule
An inflamed mass, like a knot, either raised or felt under the skin.

Pimple
A red and sensitive (inflamed) bump on the skin.

Pustule
A red and sensitive (inflamed) bump on the skin with a white or yellow center.

Whitehead
A small bump on the skin with a white center, not inflamed.

Document 3

30039215

Uses
Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

Directions
See Insert-Instructions for Use

Warnings
See Pregnancy Warning on Page 10

Operating Conditions
5 °C to 35 °C; 15%-75% Relative Humidity, non-condensing;
Atmospheric Pressure: 700-1060 hPa

Transport and Storage Between Uses Conditions
-25 °C to 45 °C; up to 75% Relative Humidity, non-condensing

Questions? 800-582-4048;
Outside US, dial collect **215-273-8755**.
www.neutrogena.com

U.S. Pat. Nos. 8771328, 9440092, 9561385, D745694, D745695

Made in China

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
Skillman, NJ 08558

Johnson & Johnson **GLOBAL STRATEGIC DESIGN OFFICE**

Document 3

File Name	30039215_NTG_LTAMask_JFU.indd				
Product Name	Neutrogena Light Therapy Acne Mask				
Date	11Aug2017	**RMC No. / Version**	30039215 /3	**Prepress Separator**	Safe Power Printing Box
Franchise	Global Beauty	**CRR Parent No.**	N/A	**Prepress Job No.**	SGS# 4612012
Brand	Neutrogena	**CRR Child No.**	258958	**Artwork Program**	InDesign CC 2015
Project Name	Tiger Updates	**PRF No.**	N/A	**Ld. Mkt. Ctry / Sales Reg.**	North America
Component Type	Insert	**Barcode No.**	0 70501 10124 7	**Language**	Single
Consumer Unit Contents	N/A	**Barcode Size**	N/A	**Printer Site**	Safe Power Printing Box
Formulation No(s).	N/A	**2D No./LCN No.**	30039215	**Decorator**	N/A
		Other Codes	N/A	**Manufacturing Site(s)**	Kin Seng
Bulk No.	N/A				
Product Code No(s) .	681012401			**Co-packer**	N/A
		Dieline No.	PGINS-0204A		

Disclaimer

- This proof indicates approximate color only!
- Printer to use pre-approved color targets.
- All structure and holding lines do not print unless otherwise indicated.
- This is prepared as a color digital mechanical, no traps have been made.
- All trapping is the responsibility of the separator and/or printer.
- Artwork must be produced from electronic file.
- UPC & data matrix are for position only. **VENDOR IS RESPONSIBLE FOR FINAL UPC AND DATA MATRIX CODE SCAN QUALITY.**

Materials & Coatings

Note: Refer to applicable Packaging Component (PC) Specification for exact details/requirements on substrates and coatings/varnishes.

ARTWORK SPECIFICS

Black | Magenta | Cyan | Yellow

Fonts	Helvetica Neue LT Std (45 Light/ 46 Light Italic/ 55 Roman/ 56 Italic/ 57 Condensed/ 65 Medium/ 75 Bold), Akzidenz-Grotesk Pro (Regular/ Bold)
Substrate	Paper
Print Methods	Offset

Graphics Production Manager

[redacted]

[redacted]@its.jnj.com [redacted]

From: Recalls
To: [redacted][JJPAU]"
Cc: [redacted]JJPAU]"
Subject: Final Email - NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Monday, 25 May 2020 11:26:33 AM

Hello [redacted]

Thank you for the follow-up email and documentation.

The recalls team considers this matter finalised and closed – no further recall action is necessary.

Kind Regards,

[redacted]
Recalls Section
Manufacturing Quality Branch

Phone: [redacted]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

Please note: you may not be aware that on 31 October 2019, the TGA launched a new, online form for sponsors to use when notifying us of new recall and non-recall actions. The online form is accessible via the TGA Business Service portal. Further advice on submitting recall information is included at Step 7 in Version 2.2 of the Uniform Recall Procedure for Therapeutic Goods (URPTG) - https://www.tga.gov.au/book-page/step-7-submitting-recall-information.

This version was published on 12 December 2019 and includes advice that the online form is now the preferred method of submitting new notifications, but we will continue to accept notifications via email **until 30 June 2020**. We look forward to receiving your future notifications via the online form and thank you in advance for your cooperation in this matter.

From: [redacted][JJPAU] [redacted]@ITS.JNJ.com>
Sent: Thursday, 14 May 2020 9:35 AM
To: Recalls <Recalls@health.gov.au>

Cc [JJPAU] <@ITS.JNJ.com>
Subject: Recall Ref # RC-2019-RN-00986-1 : Final Destruction Report [SEC=No Protective Marking]

Dear

Subsequent to our close-out report dated 12 November 2019, please find attached final report and destruction certificate of all Customer/Retailer and Consumer returned stock for Neutrogena Light Mask and Activator Kits.

Returns	Mask Kits (pcs)	Activators (pcs)
Customer and Retailer		
Consumer		
Total		

Apologies for the delay by a couple of days

We trust this completes all actions required from J&J Pacific and seek your advise if we can close the recall from our end.

Kind Regards,

Johnson & Johnson Pacific Pty. Limited
45 Jones St, Ultimo, NSW 2007, Australia
Office: | Mobile:
Email @its.jnj.com
http://www.jnj.com.au

From: Recalls <Recalls@health.gov.au>
Sent: Wednesday, 13 November 2019 4:37 PM
To: [JJPAU] <@ITS.JNJ.com>
Cc: [JJPAU] <@ITS.JNJ.com>
Subject: [EXTERNAL] Sponsor Closeout Letter - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Personal-Privacy, ACCESS=Commercial]

Hello

Please find attached the closeout report.

This recall action is now considered to be completed in accordance with the requirements of the

current Uniform Recall Procedure for Therapeutic Goods (URPTG) and has been closed on the recalls database.
I request that a final report be provided to the TGA recalls team on **11th May 2020**, providing the final number of products returned, including a final certificate of destruction.

I will follow up with you in May to confirm this information.

Please note: We are pleased to announce that Sponsors and Agents are now able to submit proposed recall actions for TGA review via TBS portal. To access the Online Web Form, please log into your TBS Portal, and go to Applications -> Recalls -> Recall/Non-Recall Submission.

Kind Regards,

[redacted]
Recalls Section
Manufacturing Quality Branch

Phone [redacted]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Sent: Tuesday, 12 November 2019 6:07 PM
To: Recalls <Recalls@health.gov.au>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: RE: Acknowledgement of Recall Ref # RC-2019-RN-00986-1: 3 month Close-Out Report [SEC=OFFICIAL]

Dear [redacted]

Further to our previous close-out report, please find attached supplement close-out report with updated data on all recalled stock highlighted in yellow.

Please also find attached 2 new destruction certificates that are representative of final returned and destroyed stock to date.

Please let us know if there's anything additional you require to facilitate the close-out of this recall.

Kind Regards,

[redacted]

Johnson & Johnson Pacific Pty. Limited
45 Jones St, Ultimo, NSW 2007, Australia
Office: [redacted] **| Mobile:** [redacted]
Email: [redacted]**@its.jnj.com**
http://www.jnj.com.au

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 14 October 2019 1:39 PM
To: [redacted][JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted][JJPAU] [redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] Acknowledgement of Recall Ref # RC-2019-RN-00986-1: 3 month Close-Out Report [SEC=OFFICIAL]

Dear [redacted]

Thank you for the close out report for the NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator recall action.

This will now be reviewed by the relevant areas within the TGA for completeness and closure and you will be contacted accordingly.

Please note that the Recalls coordinator may have additional questions and that this matter cannot be considered finalised until you have received written notification from the TGA.

We will endeavour to provide this to you as soon as possible.

Kind Regards,

[redacted]

Manufacturing Quality Branch

Phone: 02[redacted]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

www.tga.gov.au

From: [redacted] [JJPAU] [redacted]@ITS.JNJ.com>
Sent: Monday, 14 October 2019 10:31
To: Recalls <Recalls@health.gov.au>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: Recall Ref # RC-2019-RN-00986-1: 3 month Close- Out Report (Attn [redacted]
[SEC=No Protective Marking]

Dear [redacted]

In accordance with the dates assigned in the Sponsor approval letter, please find attached 3 month Close-out report and supporting documents for recall of Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - RC-2019-RN-00986-1.

Attached:

- 3 month Close-Out report
- 3 Destruction certificates
- Template of email sent to consumers

Kind Regards,

[redacted]

Johnson & Johnson Pacific Pty. Limited
45 Jones St, Ultimo, NSW 2007, Australia
Office: [redacted] **|Mobile:** [redacted]
Email: [redacted]**@its.jnj.com**
http://www.jnj.com.au

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confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Document 4

HOXTON
ABN 68 003 160 647

10 Fifteenth Ave
West Hoxton NSW 2171
P (02) 9607 6159

Certificate No. 17195-1

E-WASTE DESTRUCTION CERTIFICATE

This statutory declaration certifies the below listed goods were destroyed under secure conditions at Hoxton's site in West Hoxton.

Company Name: Johnson & Johnson
Job Reference: P17195-1

Date: 9/9/19

Delivery Date	Job Description	Weight (kg)	Destruction Date
19/8/19	Acne Mask Destruction	10,332	9/9/19
	Material Mass Balance		
	Cardboard	3,486	
	Batteries	2,934	
	Plastics	3,180	
	Circuit Board	308	
	Wire	276	
	Metal	92	
	Soft Plastics	38	
	Screen	18	

[redacted]

[redacted]

HOXTON
ABN 68 003 160 647

10 Fifteenth Ave
West Hoxton NSW 2171
P (02) 9607 6159

Certificate No. 17324-1

E-WASTE DESTRUCTION CERTIFICATE

This statutory declaration certifies the below listed goods were destroyed under secure conditions at Hoxton's site in West Hoxton.

Company Name: Johnson & Johnson
Job Reference: P17324-1

Date: 1/10/19

Delivery Date	Job Description	Weight (kg)	Destruction Date
24/9/19	Acne Mask Destruction	1,187	30/9/19
	Material Mass Balance		
	Cardboard	372	
	Batteries	366	
	Plastics	368	
	Circuit Board	38	
	Wire	28	
	Metal	12	
	Soft Plastics	1	
	Screen	2	

[redacted]

[redacted]

HOXTON
ABN 68 003 160 647

10 Fifteenth Ave
West Hoxton NSW 2171
P (02) 9607 6159

Certificate No. 17363-1

E-WASTE DESTRUCTION CERTIFICATE

This statutory declaration certifies the below listed goods were destroyed under secure conditions at Hoxton's site in West Hoxton.

Company Name: Johnson & Johnson
Job Reference: P17363-1

Date: 11/10/2019

Delivery Date	Job Description	Weight (kg)	Destruction Date
09/10/19	Acne Mask Destruction	68	11/10/19

Material Mass Balance	
Cardboard	21.32
Batteries	20.96
Plastics	21.08
Circuit Board	2.17
Wire	1.60
Metal	0.69
Soft Plastics	0.07
Screen	0.11

[redacted]

[redacted]

From: [redacted] [JJPAU]
To: [redacted] [JJPAU]
Subject: FW: Recall of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask
Date: Monday, 14 October 2019 9:24:58 AM
Attachments: image003.jpg

From: Neutrogena Mask AU
Sent: Wednesday, 9 October 2019 2:55 PM
Subject: Recall of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask

Dear Consumer

Thank you for submitting your refund request for the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask or Activator.

Our records indicate that we have not yet received your product/s - we cannot process this refund until we receive the product/s from you.

When you submitted the request for refund you would have received instructions on how to return the product/s. Please return the product/s to us as soon as possible by clicking on the Australia Post link below to complete and download your postage paid label. Please ensure that you include your Reference Number in the "Order Number" field on the form. If you do not include your unique reference number, validation of your refund will be delayed.

Australia Post Link: https://returns.auspost.com.au/jjp

If you have recently posted your product/s to us, please disregard this email.

If you have any questions regarding the returns process , please contact the Johnson & Johnson Pacific Consumer Care Centre by email NeutrogenamaskAU@its.jnj.com or free call 1800 789 348. Alternatively, please review the instructions on our website: www.neutrogena.com.au/lightmaskrecall

Thank you

Johnson & Johnson Pacific Pty Ltd

3 Month Close-out Recall Report

TGA Recall Reference number: RC-2019-RN-00986-1
Product: Neutrogena Visibly Clear Light Therapy Acne Mask and Activator
Date: 14 October 2019
Completed by: [redacted]

1. (a) Recall - Have ALL returned stock been destroyed/disposed/returned to the manufacturer*; or **(b) Correction – Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** * A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.	**[√] YES** All returned stock received to date has been destroyed. Destruction certificate are provided with this report. **a) Customer and Retail returns:** • We have received 100% reconciliation of all customer acknowledgement forms that were sent at the initiation of the recall • All stock from customer's distribution centres have been returned and destroyed. **Total units [redacted] Masks + [redacted] Activators** (Destruction certificates provided with this report) • Scan sales data have been actively monitored since the recall action was initiated. There have been no sales to consumers since initiation of the recall • All Johnson & Johnson Pacific Pty Ltd (JJP) sales representative have been provided mandatory instructions to continue to monitor retail shelves to ensure no units are present (and if necessary, remove products) • As indicated by our customers, vast majority of retail stock has been returned. For any stock that might be remaining with retail stores (but not on display), our sales reps are in the process of picking up the stock and return to our distribution centre for destruction. This is estimated to be completed in the next 2 weeks. • **JJP commits to ensuring all stock will be destroyed and any future destruction certificates will be provided as soon as destruction is complete**	**[ ] NO** Please explain & advise when this is expected to occur: Please provide list of non-responding customers:

b) Consumer returns:

- An online portal was created to facilitate a convenient method of refund and return for consumers
- **Mask claims:** To date we have received [redacted] online refund claims and [redacted] physical returns (approx. 65% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims
- **Activator claims:** To date we have received [redacted] online refund claims and [redacted] physical returns (approx. 58% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims
- For the consumers that had raised a claim but had not yet returned their goods, they were contacted by email on 9 October 2019 (Copy of email attached), to encourage them to ship the units that they have raised a claim for but have not actually posted them. The refund is issued only once the stock has been received
- A large volume of refunds were received at the initiation of the recall. Data as at Oct 14, 2019 indicates a plateau of these claims averaging to 6-7 per week. (Refer graphs below)

Document 4

- All consumer units received to date have been sent for destruction.

c) Destruction total: (This is inclusive of returned wholesale, retail and consumer units)

Destruction event	Mask kits (pcs)	Activators (pcs)
Ist destruction event		
2nd destruction event		
3rd destruction event		
Total units destroyed		

d) JJP commitment and request from TGA:

- JJP has conducted the consumer level recall as requested by the TGA.
- All commitments made by JJP have been executed and further with the additional communication to the consumers to ensure products are returned and a refund can be issued.
- To ensure our ongoing obligations under consumer law, we intend to keep the returns portal open until TGA agrees to close the recall. Irrespective, we will continue to honor any requests for refunds after that point as well
- With the return of the products from wholesalers and retailers, and a few pending destructions in the next 2 weeks, we respectfully request the TGA now consider this recall fully

	executed and closed • JJP makes this request to ensure that we can reconcile the recall in accordance with our financial obligations to our corporate body Johnson & Johnson Inc. by November end (prior to our financial year end) and therefore would sincerely appreciate if TGA would consider to close this recall by then • JJP commits to ensure any further stock that is received through the consumers returns process is destroyed in accordance to our destruction SOP • JJP will make the destruction certificates for these products available upon request	Document 4
2. What was the root cause of the defect that led to the recall/corrective action?	**Please detail:** The evaluation and risk assessment study undertaken by J&J for the theoretical risk of blue light in Neutrogena Visibly Clear Light Therapy Acne Mask did not arise from a product defect or non-conformance. The new information has been evaluated based on the HHE dated 18 June 2019. A decision was made to incorporate a new product requirement into the Risk Management File to mitigate the theoretical risk in the small subset of the population with certain underlying ocular conditions. The recall was voluntarily initiated by J&J out of an abundance of caution.	
2. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	**Please detail:** A commercial decision has been made by JJP that this generation of Neutrogena Visibly Clear Light Therapy Acne Mask and Neutrogena Visibly Clear Light Therapy Activator will be withdrawn from the market and discontinued from further supply. Additionally, this new theoretical risk will be included in the RAD (Risk Assessment Document) which will be updated to include the new information on Photobiological Effects of Blue light as a preventive action.	
3. If the response rate was not 100% at the time of the six-week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[√] YES** All customers have responded.	**[ ] NO** Please advise the % of customers that have responded……%

		And; Document 4 <u>Detail attempts made to contact remaining customers</u>

HOXTON
ABN 68 003 160 647

10 Fifteenth Ave
West Hoxton NSW 2171
P (02) 9607 6159

Certificate No. 17431-1O

E-WASTE DESTRUCTION CERTIFICATE

This statutory declaration certifies the below listed goods were destroyed under secure conditions at Hoxton's site in West Hoxton.

Company Name: Johnson & Johnson
Job Reference: P17431-1O

Date: 12/11/2019

Delivery Date	Job Description	Weight (kg)	Destruction Date
11/11/2019	Acne Mask Destruction	512	12/11/2019
	Material Mass Balance		
	Cardboard	157.1	
	Batteries	156.4	
	Plastics	156.9	
	Circuit Board	16.4	
	Wire	12.31	
	Metal	12.1	
	Soft Plastics	0.57	
	Screen	0.88	

[redacted]

[redacted]

Document 4

HOXTON
ABN 68 003 160 647

10 Fifteenth Ave
West Hoxton NSW 2171
P (02) 9607 6159

Certificate No. 17406-1

E-WASTE DESTRUCTION CERTIFICATE

This statutory declaration certifies the below listed goods were destroyed under secure conditions at Hoxton's site in West Hoxton.

Company Name: Johnson & Johnson
Job Reference: P17406-1

Date: 07/11/2019

Delivery Date	Job Description	Weight (kg)	Destruction Date
30/10/2019	Acne Mask Destruction	959	07/11/2019

Material Mass Balance	
Cardboard	303
Batteries	299
Plastics	300
Circuit Board	33.6
Wire	9.70
Metal	10.94
Soft Plastics	1.44
Screen	1.54

[redacted]

[redacted]

Johnson & Johnson Pacific Pty Ltd

Supplement Close-out Recall Report

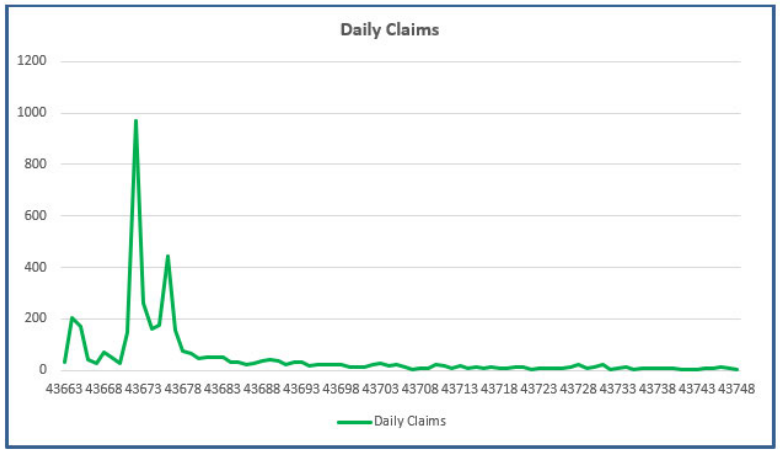
TGA Recall Reference number: RC-2019-RN-00986-1
Product: Neutrogena Visibly Clear Light Therapy Acne Mask and Activator
Date: 12 November 2019
Completed by: [redacted]

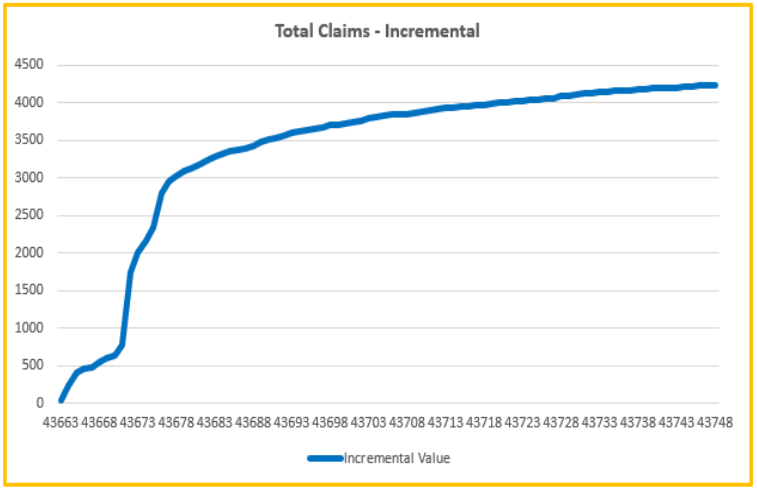
1. (a) Recall - Have ALL returned stock been destroyed/disposed/returned to the manufacturer*; or **(b) Correction – Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** * A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.	**[√] YES** All returned stock received to date has been destroyed. Note: 2 additional destruction certificates are provided with this report. **a) Customer and Retail returns:** • We have received 100% reconciliation of all customer acknowledgement forms that were sent at the initiation of the recall • All stock from customer's distribution centres have been returned and destroyed. • Scan sales data have been actively monitored since the recall action was initiated. There have been no sales to consumers since initiation of the recall • All Johnson & Johnson Pacific Pty Ltd (JJP) sales representative have been provided mandatory instructions to continue to monitor retail shelves to ensure no units are present (and if necessary, remove products) • As indicated by our customers, vast majority of retail stock has been returned. For any stock that might be remaining with retail stores (but not on display), our sales reps are in the process of picking up the stock and return to our distribution centre for destruction. This is estimated to be completed in the next 2 weeks. • **JJP commits to ensuring all stock will be destroyed and any future destruction certificates will be provided as soon as destruction is complete** **UPDATE: 12 November 2019** All additional stock from retail stores has now been received and destroyed. 2 additional destruction certificates are provided with this report.	**[ ] NO** Please explain & advise when this is expected to occur: Please provide list of non-responding customers:

Document 4

b) Consumer returns:

- An online portal was created to facilitate a convenient method of refund and return for consumers
- **Mask claims:** To date we have received [redacted] online refund claims and [redacted] physical returns (approx. 65% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims
- **Activator claims:** To date we have received [redacted] online refund claims and [redacted] physical returns (approx. 58% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims
- For the consumers that had raised a claim but had not yet returned their goods, they were contacted by email on 9 October 2019 (Copy of email attached), to encourage them to ship the units that they have raised a claim for but have not actually posted them. The refund is issued only once the stock has been received
- A large volume of refunds were received at the initiation of the recall. Data as at Oct 14, 2019 indicates a plateau of these claims averaging to 6-7 per week. (Refer graphs below)

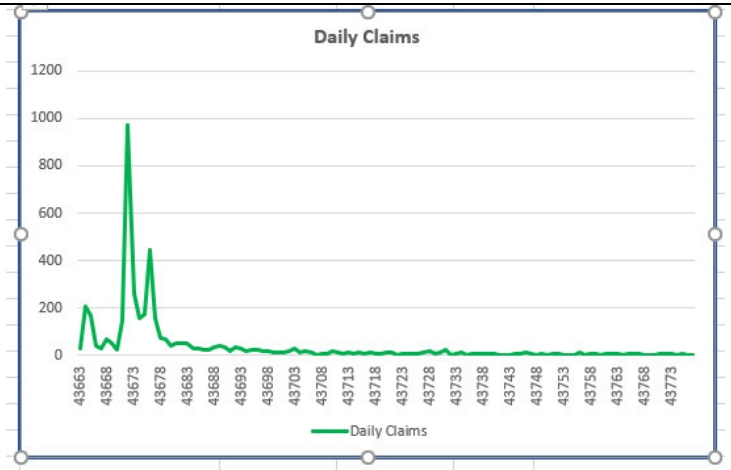


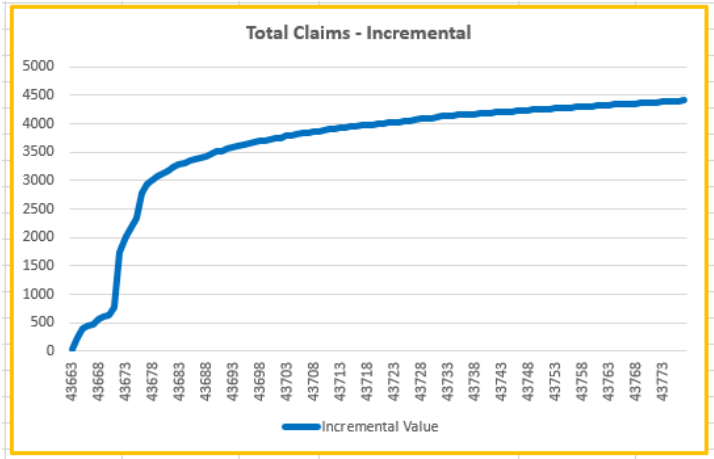


- All consumer units received to date have been sent for destruction.

UPDATE: 12 November 2019:

- **Mask claims:** To date we have received [redacted] online refund claims and [redacted] physical returns (approx. 69% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims
- **Activator claims:** To date we have received [redacted] online refund claims and [redacted] physical returns (approx. 60% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims
- All consumer returned stock has been destroyed
- Updated graphs below indicate rate as at 12 November 2019





c) Destruction total: (This is inclusive of returned wholesale, retail and consumer units)

UPDATE: 12 November 2019

Destruction event	Mask kits (pcs)	Activators (pcs)
Ist destruction event	[redacted]	
2nd destruction event		
3rd destruction event		
4th destruction event		
5th and Final destruction event		

	Total units destroyed [redacted] **d) JJP commitment and request from TGA:** • JJP has conducted the consumer level recall as requested by the TGA. • All commitments made by JJP have been executed and further with the additional communication to the consumers to ensure products are returned and a refund can be issued. • To ensure our ongoing obligations under consumer law, we intend to keep the returns portal open until TGA agrees to close the recall. Irrespective, we will continue to honor any requests for refunds after that point as well • We respectfully request the TGA now consider this recall fully executed and closed • JJP makes this request to ensure that we can reconcile the recall in accordance with our financial obligations to our corporate body Johnson & Johnson Inc. by November end (prior to our financial year end) and therefore would sincerely appreciate if TGA would consider to close this recall by then • JJP commits to ensure any further stock that is received through the consumers returns process is destroyed in accordance to our destruction SOP • JJP will retain all further destruction certificates post close-out	Document 4
2. What was the root cause of the defect that led to the recall/corrective action?	**Please detail:** The evaluation and risk assessment study undertaken by J&J for the theoretical risk of blue light in Neutrogena Visibly Clear Light Therapy Acne Mask did not arise from a product defect or non-conformance. The new information has been evaluated based on the HHE dated 18 June 2019. A decision was made to incorporate a new product requirement into the Risk Management File to mitigate the theoretical risk in the small subset of the population with certain underlying ocular conditions. The recall was voluntarily initiated by J&J out of an abundance of caution.	
2. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	**Please detail:** A commercial decision has been made by JJP that this generation of Neutrogena Visibly Clear Light Therapy Acne Mask and Neutrogena Visibly Clear Light Therapy Activator will be withdrawn from the	

	market and discontinued from further supply. Document 4 Additionally, this new theoretical risk will be included in the RAD (Risk Assessment Document) which will be updated to include the new information on Photobiological Effects of Blue light as a preventive action.	
3. If the response rate was not 100% at the time of the six-week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[√] YES** All customers have responded.	**[ ] NO** Please advise the % of customers that have responded……% And; <u>Detail attempts made to contact remaining customers</u>

Australian Government
Department of Health
Therapeutic Goods Administration

In reply please quote: RC-2019-RN-00986-1

Managing Director
Johnson & Johnson Pacific Pty Ltd

Attention [redacted]
13/11/20

Dear Sir/Madam,

Subject: Close Out Letter to Sponsor

NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator

Neutrogena Visibly Clear Light Therapy Acne Mask
SAP Code: 26202031

Neutrogena Visibly Clear Light Therapy Acne Mask Activator
SAP Codes: 26202032 and 26202034

ARTG: 287825
(Johnson & Johnson Pacific Pty Ltd - Red/blue light phototherapy unit)

Thank you for your final report regarding the recall action involving the above therapeutic good(s).

Copies of the close out reports have now been reviewed by the TGA's Recalls Section regarding the effectiveness of the recall action itself. This information will also be used as part of ongoing monitoring and compliance activities undertaken by the TGA.

This recall action is now considered to be completed in accordance with the requirements of the current Uniform Recall Procedure for Therapeutic Goods (URPTG) and has been closed on the recalls database.

As part of finalising this action, the TGA Recalls Section is requesting that Sponsors verify the staff contact details given in the TBS Portal are up to date as per the guidance given in this link: https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators

I also request that a final report be provided to the TGA recalls team on 11th May 2020, providing the final number of products returned, including a final certificate of destruction.

Please do not hesitate to contact me on the numbers below if you have any further concerns on this issue.

Yours sincerely,

[redacted]
Recalls Section
Manufacturing Quality Branch

Phone: 02[redacted]
Email: Recalls@health.gov.au

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

(Signed electronically)

HOXTON
ABN 68 003 160 647

10 Fifteenth Ave
West Hoxton NSW 2171
P (02) 9607 6159

Certificate No. 17906-1O

E-WASTE DESTRUCTION CERTIFICATE

This statutory declaration certifies the below listed goods were destroyed under secure conditions at Hoxton's site in West Hoxton.

Company Name: Johnson & Johnson
Job Reference: P17906-1O

Date: 29/04/20

Delivery Date	Job Description	Weight (kg)	Destruction Date
22/04/20	Acne Mask Destruction	165	29/04/20
	Material Mass Balance		
	Cardboard	51.73	
	Batteries	50.86	
	Plastics	51.15	
	Circuit Board	5.26	
	Wire	3.88	
	Metal	1.68	
	Soft Plastics	0.17	
	Screen	0.27	

[redacted]

Johnson & Johnson Pacific Pty Ltd – Final Report

Document 4

TGA Recall Reference number: RC-2019-RN-00986-1
Product: Neutrogena Visibly Clear Light Therapy Acne Mask and Activator
Date: 14 May 2020
Completed by: [redacted]

(a) Recall - Have ALL returned stock been destroyed/disposed/returned to the manufacturer*; or **(b) Correction – Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** * A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.	**[√] YES** Subsequent to our previous report dated 12 November 2019, below is summary of all stock received and destroyed. Destruction certificates attached. **a) Customer and Retail returns:** • We have received 100% reconciliation of all customer acknowledgement forms that were sent at the initiation of the recall • All stock from customer's distribution centres and retail stores have been returned and destroyed. **b) Consumer returns:** • **Mask claims:** To date we have received a total of [redacted] online refund claims and [redacted] physical returns (approx. 70% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims • **Activator claims:** To date we have received a total of [redacted] online refund claims and [redacted] physical returns (approx. 61% of claims have been physically returned). We are aware of some duplicates and possible fraudulent claims • All consumer returned stock has been destroyed **c) Units received and destroyed post 12 November 2019:** [redacted]	**[ ] NO** Please explain & advise when this is expected to occur: Please provide list of non-responding customers:

Returns	Mask Kits (pcs)	Activators (pcs)
Customer	[redacted]	[redacted]
Consumer		
Total		

From: [redacted] [JJPAU]
To: Recalls
Subject: Website Active Date- Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 18 July 2019 8:37:00 AM
Attachments: FINAL JJP Consumer Level Communication Strategy 170719.docx
FINAL NLTAM Consumer Letter 170719.docx
FINAL NLTAM Consumer Recall Notice 170719.DOCX
FINAL NLTAM Industry Association Letter 170719.docx
FINAL NLTAM Internal field messages 170719.docx
FINAL NLTAM Recall Acknowledgement Form 170719.docx
FINAL NLTAM Retail Letter 170719.docx
FINAL NLTAM social and website copy 170719.pptx
FINAL NLTAM Wholesale Letter 170719.docx
Website - REFUND FOR THE RECALLED NLTAM.pdf

Hi [redacted]

I can now confirm that https://www.neutrogena.com.au/lightmaskrecall is now live and we have already started having consumers requesting refunds through the website. For your records, have attached a PDF version of the Webpage

I have also attached the final communication strategy document – [FINAL JJP Consumer level Communication Strategy 170719.docx] as well as the final versions of each of the documents referenced in the strategy document. These are:

- TGA Recall Notice (black box) – [*FINAL NLTAM Consumer Recall Notice 170719.docx*]
- Wholesaler letter – [*FINAL NLTAM Wholesale Letter 170719.docx*]
- Retailer letter – [*FINAL NLTAM Retail Letter 170719.docx*]
- Consumer letter– [*FINAL NLTAM Consumer Letter 170719.docx*]
- Industry association letter – [*FINAL NLTAM Industry Association Letter 170719.docx*]
- Recall acknowledgement form – [*FINAL NLTAM Recall Acknowledgement Form 170719.docx*]
- Social media and website copy – [*FINAL NLTAM Social and Website Copy 170719.pptx*]
- Internal communications for field team – [*FINAL NLTAM Internal field messages 170719.docx*]

Please let me know if you need anything further from me

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Wednesday, 17 July 2019 4:33 PM
To: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] Website Active Date- Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank you for the update.

Do you know when the https://www.neutrogena.com.au/lightmaskrecall site will be active?

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted][JJPAU] [mailto[redacted]@ITS.JNJ.com]
Sent: Wednesday, 17 July 2019 10:58 AM
Subject: RE: Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Please see attached signed version of the retail and wholesale letter.

We will come back to you on the Comms strategy document with the requested amendments/corrections

Kind Regards

[redacted]

[redacted]
Pacific & North Asia

Johnson & Johnson Pacific

Locked Bag 5, BROADWAY NSW 2007 AUSTRALIA
45 Jones Street ULTIMO NSW 2007 AUSTRALIA
Tel: [redacted] | Mobile: [redacted]
Email: [redacted]@its.jnj.com

From: [redacted] [JJPAU]
Sent: Wednesday, 17 July 2019 10:35 AM
To: 'Recalls' <Recalls@health.gov.au>
Subject: RE: Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

As per our discussion – we made changes to advise consumer to go directly to the website - - to help you with the update, please see the below text

In alignment with the recommendation of the TGA, consumers who have purchased these devices, should immediately discontinue use. To return the devices and obtain a refund consumers should visit www.neutrogena.com.au/lightmaskrecall.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348

Kind regards

[redacted]

From: [redacted] [JJPAU]
Sent: Tuesday, 16 July 2019 5:15 PM
To: Recalls <Recalls@health.gov.au>
Subject: RE: Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

We have been doing some reviews of the email approach…we are thinking it will be easier for the consumer to actually go directly to the website to arrange the return and refund.

We are going to update all of our communications to reflect this change in approach – it will take out 2 steps in the process, so will definitely make things easier.

I hope this is OK – we will share the updated documents with you (basically replacing the Neutrogena email address with the Neutrogena-recall website)

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Tuesday, 16 July 2019 4:31 PM
To [redacted][JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

As discussed. Please find attached the relevant documents that will be issued as part of the agreed up communication strategy.

If there is any missing or incorrect information – please notify me ASAP.

Please confirm that the names of the documents within page 3 of the consumer level communication strategy are the same as attached and used in page 5 of the consumer level communication strategy.

Please provide any missing documents to be released (e.g. industry association letter).

ATTACHED DOCUMENTS:

Attachment Number	Document Name (In communication strategy)	Document Name (As Attached)
1	Communication Strategy	Sponsor Consumer Level Communication Strategy
2	TGA Recall Notice (black box)	Draft NLTAM consumer recall Notice
3	Wholesaler letter	Wholesale Letter
4	Retailer letter	Retailer letter
5	Recall acknowledgement form	Acknowledgement Form
6	Social media post	NLTAM social post

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Tuesday, 16 July 2019 2:53 PM
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

When you get a chance, could you please give me a call – [redacted] (it is not urgent). I just want to make sure you have everything you need from us and to seek feedback on the various consumer communications (particularly if I need to send anything up to my global counterparts for review and approval)

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Tuesday, 16 July 2019 10:58 AM
To: [redacted] [JJPAU] [redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank you for the updated information.

After looking at the MO edited version, I have made the following changes to your feedback below:

Comment 1: - This sentence was removed (e.g. removal of "**including people with enhanced light sensitivity"**)

Comment 2: This entire sentence was removed on the first MO revision of the document – TGA does not include statements of sponsors database as we cannot confirm this.

Please see the final attached document that will be sent for approval to the Director of the TGA Recalls section.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Tuesday, 16 July 2019 10:50 AM
To: Recalls
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

As per our conversation, the feedback I have from my Chief medical officer are as follows:

Paragraph 4 – "including people with enhanced light sensitivity"
Comment: The HHE does not list those with enhanced light sensitivity as at risk of permanent retinal injury. Those with certain ocular disorders which are listed are expected to have enhanced light sensitivity but including the statement as written is not consistent with the HHE.

Paragraph 4 – Suggested inclusion from JJP: Within Johnson & Johnson database we do not have any adverse events related to these potential risk conditions.
Comment: From a factual perspective, it would be best to represent this statement as "There are no reports in the company's safety database associated with the device that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users."
This wording may not be ideal from a consumer perspective – but we are of the view that this should be as factual as possible – the initial suggested change is not as clear/factual

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 15 July 2019 4:53 PM
To: [redacted][JJPAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

This is acceptable.

Please note – This web-statement was generated after TGA MO and TGA Communications Team Review.
The TGA will consider all suggested changes relating to technical issues and any errors of fact.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Monday, 15 July 2019 4:43 PM
To: Recalls
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

We have been circulating this internally, and I am going to need to send this up to my global colleagues for comment – Especially given the paragraph about the misuse and the potential device personalisation.

I will receive feedback overnight – so if we could hold until 9 am tomorrow morning, I would be most grateful

Thanks for your understanding

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 15 July 2019 1:21 PM
To [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Please find attached the TGA's draft web statement regarding the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator.

Could you please check for technical issues and to ensure accuracy and provide the TGA feedback by **COB TODAY 15th JULY 2019.**

Please note that this statement is aimed at both consumers and health professionals.

The TGA will consider all suggested changes relating to technical issues and any errors of fact.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

OVERVIEW & KEY MESSAGES

- **Description of product**:
  The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask (Starter Kit, Model 31000) is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of red and blue light via light-emitting diodes (LEDs), and weighs less than 400g.

  The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator (Model 71000) is offered separately to increase the number of doses available from the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries.

- **Description of Issue**:
  As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

  Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient.

  There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

  Description of Health Risks:
  For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk that varying degrees of peripheral retinal damage could occur.

- **Description of Consumer Actions to be Taken**:
  Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration, is recalling the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator. This action is being taken as a precautionary measure.

  In alignment with the recommendation of the TGA, Consumers in Australia who have purchased the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator should discontinue use.

  Consumers can return the devices by contacting the Johnson & Johnson Pacific Consumer Care Centre at neutrogenamaskAU@its.jnj.com or 1800 789 348

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

- **Contact Information for Consumers**:
  Email Johnson & Johnson Pacific Consumer Care Centre at neutrogenamaskAU@its.jnj.com for refunds and returns
  Phone Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348

  Consumers experiencing any adverse symptoms should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com.

- **Method of Product Recovery, Disposal or Correction:**
  If consumers have purchased the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator, they should contact the Johnson & Johnson Pacific Consumer Care Centre via email neutrogenamaskAU@its.jnj.com or call 1800 789 348 to arrange the return of devices and obtain refund.

  Johnson & Johnson Pacific (JJP) will arrange for the destruction of all devices with a suitable environmentally friendly disposal vendor.

  A decision has been made to globally discontinue the current generation of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask due to the fact the product underperformed commercially.

COMMUNICATIONS OBJECTIVES

- **Communications objectives**:
  - To ensure consumers who have purchased the devices are aware of the field action, know how to return the devices and obtain a refund
  - To ensure retailers know how to return the devices and obtain a credit from their wholesaler
  - To ensure wholesalers know how to return the devices and obtain a credit from JJP

- **Estimated Outcome (including timeframe):**
  A recall effectiveness at the wholesaler level of 90% is anticipated. JJP does not have visibility of the complete list of retailers that are part of each wholesaler's network. Wholesalers will be required with to contact all of their retailers and provide:
  - Number of retailers successfully contacted that received a complete recall package via returned acknowledgement forms
  - Total number of units at retailer's inventory at the time of notification
  - Total number of units returned to wholesaler by each retailer.

  Since activators are disposable, we anticipate that customers will have only on hand the ones they are using. For both the mask and the activators we are providing incentive to return them in the form of a refund.

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

COMMUNICATIONS ASSETS TO BE PRODUCED (To be confirmed upon review and approval by TGA)

- TGA Recall Notice (black box) – [*FINAL NLTAM Consumer Recall Notice 170719.docx*]
- Wholesaler letter – [*FINAL NLTAM Wholesale Letter 170719.docx*]
- Retailer letter – [*FINAL NLTAM Retail Letter 170719.docx*]
- Consumer letter– [*FINAL NLTAM Consumer Letter 170719.docx*]
- Industry association letter – [*FINAL NLTAM Industry Association Letter 170719.docx*]
- Recall acknowledgement form – [*FINAL NLTAM Recall Acknowledgement Form 170719.docx*]
- Social media and website copy – [*FINAL NLTAM Social and Website Copy 170719.pptx*]
- Internal communications for field team – [*FINAL NLTAM Internal field messages 170719.docx*]

KEY TIMINGS

Dates are indicative only. Final dates to be agreed following final consultation with TGA

- Action: Communications to be finalised in consultation with TGA by Monday 16 July 2019 (COMPLETED)
- Action: JJP field team to be briefed on Wednesday 17 July 2019 (COMPLETED)
- Action: Phone calls with wholesaler customers followed by wholesaler letters, retailer letters and acknowledgement forms to be emailed to customers to commence on Wednesday 17 July 2019
- Action: Refunds website to be live Wednesday 17 July 2019
- Action: Social and website posts to be uploaded on Wednesday 17 July 2019
- Action: Industry groups to be notified on Thursday 18 July 2019

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

RATIONALE FOR CONSUMER CHANNEL SELECTION

The core audience for the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is females aged 16-35. This demographic over-indexes against digital, including social media. This, along with market intelligence on audience media behaviours, has informed the decision to invest almost 100% of marketing spend in digital channels since the mask was launched in August 2017.

The average monthly sales to consumers are approximately [redacted] units of the mask and [redacted] activators. Each activator contains 30 days use. **We therefore estimate that there only [redacted] masks currently in use**.

Our communications strategy is focused on using the most effective channels to reach our audience ie digital and social to target those who have purchased the mask, ensuring the highest chance of visibility to current users.

The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator is a **pharmacy-only product** in Australia. [redacted]

We propose to send a consumer letter through Chemist Warehouse and Priceline databases to all consumers who have purchased the devices via e-commerce or through their loyalty schemes, for example Priceline's "Sister Club". Please note that given we have not communicated this to Priceline or Chemist Warehouse, we need to confirm when and how this could be done.

A combination of Facebook and Instagram posts provides the most effective reach for our audience. Posts with information on the recall will be shown on Facebook and Instagram where 60% of this audience is.

A global decision has been made to display a recall notice on all Neutrogena websites in countries where the mask is sold.

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

COMMUNICATIONS STAKEHOLDER TIMEFRAME MATRIX:

STAKEHOLDER	What/Action	Media outlet/channel	Signature	DATE
EXTERNAL				
Wholesalers	Send wholesale letter, retail letter and recall acknowledgement forms to all wholesalers	*FINAL NLTAM Wholesale Letter 170719.docx* *FINAL NLTAM Retail Letter 170719.docx* *FINAL NLTAM Recall Acknowledgement Form 170719.docx*	[Signature]	170719
Retailers	Wholesalers to send retail letter to all retailers	*FINAL NLTAM Retail Letter 170719.docx*	[Signature]	170719
Priceline and Chemist Warehouse customers [redacted]	Consumer letter to be sent to Chemist Warehouse and Priceline databases to consumers who have purchased the devices through e-commerce or through their loyalty schemes, for example Priceline's "Sister Club".	*FINAL NLTAM Consumer Letter 170719.docx*	[Signature]	180719
All other e-retailers eg Amazon	Place consumer letter with information for consumers on e-commerce site	*FINAL NLTAM Consumer Letter 170719.docx*	[Signature]	180719
Consumers	Social media post – copy plus recall notice	*FINAL NLTAM Social and Website Copy 170719.pptx* Neutrogena AU Facebook (5.2m followers) Neutrogena AU Instagram (8k followers)	[Signature]	170719
Consumers	Website post – TGA recall notice Website post – consumer website copy	*FINAL NLTAM Consumer Recall Notice 170719.docx* *FINAL NLTAM Social and Website Copy 170719.pptx* Neutrogena.com.au – home page Neutrogena.com.au – product page	[Signature]	170719
TGA website	Website post - recall alert	TGA website	[Signature]	170719
GOV/INDUSTRY CONTACTS				
Consumer Health Products Australia	Industry association letter	*FINAL NLTAM Industry Association Letter 170719.docx*	[Signature]	180719
ACCORD	Industry association letter	*FINAL NLTAM Industry Association Letter 170719.docx*	[Signature]	180719
MTAA	Industry association letter	*FINAL NLTAM Industry Association Letter 170719.docx*	[Signature]	180719

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

INTERNAL				
All employees	Brief all employees	*FINAL NLTAM Internal field messages 170719.docx* Face to face and phone calls	[Signature]	170719
Internal field and HCP teams	Brief the field and HCP teams	*FINAL NLTAM Internal field messages 170719.docx* Phone call to be followed up with email with wholesaler letter, retailer letter, recall acknowledgement form	[Signature]	170719
Consumer Care Centre	Brief the CCC team	*FINAL NLTAM Internal field messages 170719.docx* Phone call	[Signature]	170719
Staff shops	Complete retailer recall process	*FINAL NLTAM Retail Letter 170719.docx*	[Signature]	170719

Date: 17 July 2019

Recall Notice for Consumers

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and Activator

Dear Valued Consumer,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Activator at a consumer level in Australia. We are contacting you because may have purchased these products.

Affected devices:

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask on the eye.

This action has been taken as a precautionary measure.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear™ Light Therapy Acne Spot Treatment; consumers can continue to use the Spot Treatment as directed.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Action to be taken by consumers:

This notice applies to all NEUTROGENA® Visibly Clear Light Therapy Acne Masks and Activators.

In alignment with the recommendation of the TGA, if you have purchased these devices, please discontinue use. To return the devices and obtain a refund visit www.neutrogena.com.au/lightmaskrecall.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products, which is why we voluntarily initiated this action.

[redacted]

[redacted]
Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE MASK AND ACTIVATOR

ARTG ID: 287825

TGA Recall Reference: RC-2019-RN-00986-1

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), is recalling the NEUTROGENA Visibly Clear Light Therapy Acne Mask (a battery powered mask worn by consumers that emits both red and blue light for the treatment of mild to moderate acne) and NEUTROGENA Visibly Clear Light Therapy Acne Mask Activator.

Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the Mask on the eye.

It has been identified that there is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance the eye's sensitivity to light.

If you have purchased any of these devices, immediately discontinue use.

To return the devices and obtain a refund visit www.neutrogena.com.au/lightmaskrecall.

If you experience any adverse symptoms, you should contact your healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348.

Johnson & Johnson Pacific Pty Ltd sincerely regrets any inconvenience to its consumers.

Date: 18 July 2019

Recall notice for the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and Activator

Dear Industry Association,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Activator at a consumer level in Australia.

We are contacting you because you may be contacted by a healthcare professional asking about these devices or a consumer who has purchased or used these devices.

Affected devices:

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask on the eye.

This action has been taken as a precautionary measure.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear™ Light Therapy Acne Spot Treatment - consumers can continue to use the Spot Treatment as directed.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Action to be taken by consumers:

This notice applies to all NEUTROGENA® Visibly Clear Light Therapy Acne Masks and Activators.

In alignment with the recommendation of the TGA, if consumers have purchased these devices, please instruct them to immediately discontinue use. To return the devices and obtain a refund consumers should visit www.neutrogena.com.au/lightmaskrecall.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products, which is why we voluntarily initiated this action.

[redacted]

[redacted]
Johnson & Johnson Pacific

KEY MESSAGES FOR AU BUSINESS MANAGERS

- We want to update you on a field action taking place today in Australia on the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator.

- Following consultation with the Australian regulator, TGA, we have made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator at the consumer level.

- As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask on the eye.

- There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

- This recall is being conducted as a precautionary measure.

- The Mask and Activator are being withdrawn and will no longer be supplied.

- This recall does not apply to the Acne spot treatment.

- At Johnson & Johnson Consumer, our first priority is the health and safety of those who use our products, which is why we voluntarily initiated this action.

- Thank you for your support in helping us to manage this field action.

Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask

and NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask Activator

AFFECTED DEVICES:

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

On behalf of this organisation I acknowledge receipt of the Medical Device Recall notice date Wednesday 17th July 2019 relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	**Batch/Lot/Date**	**Quantity of stock received**	**Quantity of unused stock subject to recall (currently in quarantine)**
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator			
Neutrogena Visibly Clear Light Therapy Acne Mask Activator			
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Name	[redacted]
Position	[redacted]
Organisation	Johnson & Johnson Pacific
Address	45 Jones Street, Ultimo NSW 2007
Email	[redacted]@its.jnj.com
Subject of email	Neutrogena Visibly Clear Light Therapy Acne Mask and Activator
Telephone no.	1800 638 047 (press '2')

Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: 17 July 2019

Dear Retailer,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear™ Light Therapy Acne Spot Treatment.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask on the eye.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Retailers are advised that the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Activator are being withdrawn and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers who have purchased these devices, should immediately discontinue use. To return the devices and obtain a refund consumers should visit www.neutrogena.com.au/lightmaskrecall.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348.

Actions to be taken:

We understand that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further distribution;
- Complete the **Recall Acknowledgement Form** (attached) immediately whether you have stock or not;
- Return the acknowledgement form with your existing inventory to the wholesaler you obtained it from and arrange for a credit;
- Please direct all consumer returns to the following website www.neutrogena.com.au/lightmaskrecall to organise the return of all affected devices and arrange a refund.

Ensure relevant staff members are informed of this recall.

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing a copy of this letter and the Recall Acknowledgment Form.

Johnson & Johnson Pacific

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products which is why we have voluntarily initiated this action.

Yours sincerely

Johnson & Johnson Pacific

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Facebook and Instagram

Recall notice for consumers in Australia

You may have noticed that the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and Activator are not available where you shop in Australia. That's because these products have been recalled.

This action is being undertaken as a precautionary measure.

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the Mask on the eye.

It has been identified that there is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance the eye's sensitivity to light. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

In alignment with the recommendation of the TGA, if you have purchased these devices, immediately discontinue use. To return the devices and obtain a refund visit www.neutrogena.com.au/lightmaskrecall

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348.

Johnson & Johnson Pacific sincerely regrets any inconvenience to its consumers.

Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: 17 July 2019.

Dear [customer name],

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear™ Light Therapy Acne Spot Treatment.

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask on the eye.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Customers are advised that the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Activator are being withdrawn and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers who have purchased these devices should immediately discontinue use. To return the devices and obtain a refund, consumers should visit www.neutrogena.com.au/lightmaskrecall.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348.

Actions to be taken:

Our records show that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further distribution;
- Complete the **Recall Acknowledgement Form** (attached) immediately, whether you have affected medical devices or not and return the form to **CustomerService2@ITS.JNJ.COM** ;
- If the affected medical devices have been forwarded to a retail store, contact that retailer with the attached **Letter to Retailers** and the **Recall Acknowledgement Form**, which they need to fill in and return to you, whether they have affected medical devices or not;
- Before you raise a credit claim, please ensure you have collected all acknowledgement forms and affected devices from your retailers;
- Raise a credit claim in your system and email the claim and the consolidated Acknowledgement Forms to **CustomerService2@ITS.JNJ.COM;**
- Once the claim has been received, Johnson & Johnson Pacific Customer Service will contact you to provide your return number and pick up instructions.

Johnson & Johnson Pacific

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products, which is why we have voluntarily initiated this process.

If you have any other questions, please don't hesitate to contact your business manager.

Yours sincerely

Johnson & Johnson Pacific

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Document 12

SEARCH

Home > Light Mask Recall

REFUND FOR THE RECALLED NEUTROGENA® VISIBLY CLEAR™ LIGHT THERAPY ACNE MASK AND NEUTROGENA® VISIBLY CLEAR™ LIGHT THERAPY ACNE MASK ACTIVATOR

This is a page for consumers in Australia to obtain a refund for the recalled NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask and NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask Activator. The refund will be for the amount specified in the terms and conditions referred to below.

To claim a refund you must:

1. Be a consumer in Australia who has purchased the NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask or NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask Activator in Australia;
2. provide the information requested in the form below (if you do not provide this information we cannot provide the refund); and
3. return the products to us following the instructions in the confirmation email we will send to you.

Once you submit the information below, you will receive an email with further details on how you can obtain a refund. If you don't receive that email, please check your junk mail and, if you still do not have the email (or are having any difficulty with this site), contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348.

The process (once you receive the confirmation email):

1. Your confirmation email will include details of how the products must be returned and your **unique reference number.**
2. You will also receive a **link** to an Australia Post postage label form.
3. Click on the Australia Post link to complete and download your postage paid label. Please ensure you include your **unique reference number** in the "Order Number" field on the form. If you do not include your unique reference number, the validation of your refund will be delayed.
4. Then print the postage label and attach it to the front of the package containing the products being returned and post the package. You must return all products in one package.

Please click here to view the full Terms and Conditions and click here to view the Privacy Statement.

Document 12

Please fill in the fields below:

First Name *

Last Name *

Email Address *

Phone Number *

Street Address *

Suburb Town *

State * Please select...

Quantity of NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask Kits being returned (Kit includes (1) Mask and (1) Mask Activator): * Please select...

Quantity of additional NEUTROGENA® Visibly Clear™ Light Therapy Acne Mask Activators being returned (Mask Activator ONLY): * Please select...

Please select your preferred refund mechanism *

- Virtual Visa card (redeemable only by phone or online, not in store)

Document 12

- [ ] Physical eftpos card (redeemable at any retailer that accepts eftpos)

Neutrogena sincerely regrets any inconvenience to its consumers.

Please confirm the following:

- [ ] I have read and accept the Privacy Statement for this refund

- [ ] I have read and accept the Terms & Conditions for this refund

Privacy Statement:

We collect your personal information to process your refund for Neutrogena® Visibly Clear Light Therapy Acne Mask and/or Neutrogena® Visibly Clear Light Therapy Acne Mask Activator and for related administrative purposes. Without this information we are unable to process your refund. Your personal information may also be processed by our contracted service providers who assist us from time to time with administrative tasks. These service providers are subject to contractual measures to safeguard and protect your personal information consistent with Australian privacy laws. Subject to some exceptions permitted by law you may request access to, or correction of, your personal information. For further information about our privacy practices please go to https://www.neutrogena.com.au/privacy-policy

Submit

From: [redacted] [JJPAU]
To: Recalls
Subject: Re: Website Active Date- Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Wednesday, 17 July 2019 4:45:59 PM

Hi [redacted]

It supposed to be going live this afternoon - our team in Singapore are activating this - I will keep you up to date (there might be an interim holding page if there are any technical issues (which we don't think there will be))

The "black triangle" is now live on our NEUTROGENA website

Comms strategy document has been updated - I am reviewing and plan to send either today or first thing tomorrow

Kind regards

[redacted]
Sent from my iPhone

On 17 Jul 2019, at 16:33, Recalls <Recalls@health.gov.au> wrote:

> Dear [redacted]
>
> Thank you for the update.
>
> Do you know when the https://www.neutrogena.com.au/lightmaskrecall site will be active?
>
> Kind Regards,
>
> [redacted]
> Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
> Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au
>
> Therapeutic Goods Administration
> Department of Health
> PO Box 100
> Woden ACT 2606
> www.tga.gov.au
>
> <image001.jpg>
> *This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Wednesday, 17 July 2019 10:58 AM
Subject: RE: Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Please see attached signed version of the retail and wholesale letter.

We will come back to you on the Comms strategy document with the requested amendments/corrections

Kind Regards

[redacted]

[redacted]
Pacific & North Asia

Johnson & Johnson Pacific
Locked Bag 5, BROADWAY NSW 2007 AUSTRALIA
45 Jones Street ULTIMO NSW 2007 AUSTRALIA
Tel: [redacted] | Mobile: [redacted]
Email: [redacted]@its.jnj.com

From: [redacted] [JJPAU]
Sent: Wednesday, 17 July 2019 10:35 AM
To: 'Recalls' <Recalls@health.gov.au>
Subject: RE: Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

As per our discussion – we made changes to advise consumer to go directly to the website - - to help you with the update, please see the below text

In alignment with the recommendation of the TGA, consumers who have purchased these devices, should immediately discontinue use. To return the devices and obtain a refund consumers should visit www.neutrogena.com.au/lightmaskrecall.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident at www.jnj.com.au/contact-us or call 1800 789 348

Kind regards

[redacted]

From: [redacted] [JJPAU]
Sent: Tuesday, 16 July 2019 5:15 PM
To: Recalls <Recalls@health.gov.au>
Subject: RE: Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

We have been doing some reviews of the email approach…we are thinking it will be easier for the consumer to actually go directly to the website to arrange the return and refund.

We are going to update all of our communications to reflect this change in approach – it will take out 2 steps in the process, so will definitely make things easier.

I hope this is OK – we will share the updated documents with you (basically replacing the Neutrogena email address with the Neutrogena-recall website)

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Tuesday, 16 July 2019 4:31 PM
To: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] Communication Strategy Documents - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

As discussed. Please find attached the relevant documents that will be issued as part of the agreed up communication strategy.

If there is any missing or incorrect information – please notify me ASAP.

Please confirm that the names of the documents within page 3 of the consumer

level communication strategy are the same as attached and used in page 5 of the consumer level communication strategy.

Please provide any missing documents to be released (e.g. industry association letter).

ATTACHED DOCUMENTS:

Attachment Number	Document Name (In communication strategy)	Document Name (As Attached)
1	Communication Strategy	Sponsor Consumer Level Communication Strategy
2	TGA Recall Notice (black box)	Draft NLTAM consumer recall Notice
3	Wholesaler letter	Wholesale Letter
4	Retailer letter	Retailer letter
5	Recall acknowledgement form	Acknowledgement Form
6	Social media post	NLTAM social post

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

<image001.jpg>

From: [redacted][JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Tuesday, 16 July 2019 2:53 PM
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

When you get a chance, could you please give me a call – [redacted](it is not

urgent). I just want to make sure you have everything you need from us and to seek feedback on the various consumer communications (particularly if I need to send anything up to my global counterparts for review and approval)

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Tuesday, 16 July 2019 10:58 AM
To: [redacted] [JJPAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dea [redacted]

Thank you for the updated information.

After looking at the MO edited version, I have made the following changes to your feedback below:

Comment 1: - This sentence was removed (e.g. removal of "**including people with enhanced light sensitivity"**)

Comment 2: This entire sentence was removed on the first MO revision of the document – TGA does not include statements of sponsors database as we cannot confirm this.

Please see the final attached document that will be sent for approval to the Director of the TGA Recalls section.

Kind Regards,

[redacted]

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

<image001.jpg>

legislative requirements are met.

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Tuesday, 16 July 2019 10:50 AM
To: Recalls
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

As per our conversation, the feedback I have from my Chief medical officer are as follows:

Paragraph 4 – "including people with enhanced light sensitivity"
Comment: The HHE does not list those with enhanced light sensitivity as at risk of permanent retinal injury. Those with certain ocular disorders which are listed are expected to have enhanced light sensitivity but including the statement as written is not consistent with the HHE.

Paragraph 4 – Suggested inclusion from JJP: Within Johnson & Johnson database we do not have any adverse events related to these potential risk conditions.
Comment: From a factual perspective, it would be best to represent this statement as "There are no reports in the company's safety database associated with the device that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users."
This wording may not be ideal from a consumer perspective – but we are of the view that this should be as factual as possible – the initial suggested change is not as clear/factual

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 15 July 2019 4:53 PM
To: [redacted] [JJPAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

This is acceptable.

Please note – This web-statement was generated after TGA MO and TGA Communications Team Review.

The TGA will consider all suggested changes relating to technical issues and any errors of fact.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

<image001.jpg>

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Monday, 15 July 2019 4:43 PM
To: Recalls
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

We have been circulating this internally, and I am going to need to send this up to my global colleagues for comment – Especially given the paragraph about the misuse and the potential device personalisation.

I will receive feedback overnight – so if we could hold until 9 am tomorrow morning, I would be most grateful

Thanks for your understanding

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 15 July 2019 1:21 PM
To: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Please find attached the TGA's draft web statement regarding the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator.

Could you please check for technical issues and to ensure accuracy and provide the TGA feedback by **COB TODAY 15th JULY 2019.**

Please note that this statement is aimed at both consumers and health professionals.

The TGA will consider all suggested changes relating to technical issues and any errors of fact.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

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<image001.jpg>

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

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From: Recalls
To: [redacted][JJPAU]"
Subject: UPDATED - Sponsor Agreement Letter - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Tuesday, 16 July 2019 4:14:09 PM
Attachments: UPDATED - Sponsor Agreement Letter - RC-2019-RN-00986-1.pdf

---

Dear [redacted]

As discussed over the phone – please find an updated agreement letter.
All changes made are highlighted in red – these will be displayed on our SARA database.
(The TGA Web-statement Link will be added once it is approved and uploaded).

No changes to dates have been made (e.g. agreement date).

The communication strategy document will be provided shortly.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: Recalls [mailto:Recalls@health.gov.au]
Sent: Monday, 15 July 2019 10:18 AM
Subject: RE: Sponsor Agreement Letter - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank you for the emails last week.

I will reply to each one individually to make sure I provide an answer for each of your questions/changes.

Request 1:
The subject information is not posted online or to any of the state or territory coordinators –

only for your companies eyes as a subject header.
This information will not be changed.

Request 2:
I have changed the wording on our online database to the following:
Johnson & Johnson Pacific have advised that following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, J&J further evaluated the potential effects of the NEUTROGENA Visibly Clear Light Therapy Acne Mask on the eye.

J&J identified that for a small subset of the population with certain underlying eye conditions (such as retinitis pigmentosa, ocular albinism or other hereditary ocular disorders) or users taking medications which could enhance ocular photosensitivity, there exists a theoretical potential risk of be varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision

JJP has advised that this generation of the NEUTROGENA Visibly Clear Light Therapy Acne Mask and NEUTROGENA Visibly Clear Light Therapy Activator are being withdrawn from the market and will no longer be supplied.

The only change I have made from your proposed wording is the removing of the following sentence:
This recall is being conducted as a precautionary measure.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Friday, 12 July 2019 3:27 PM
To: Recalls
Cc: [redacted] [JJPAU]

Subject: RE: Sponsor Agreement Letter - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Thanks for your time today to discuss the communication strategy. I will send this through to you later today.

With regard to the sponsor agreement letter, if possible I would like to request a few changes to ensure consistency with our previous communications and with the position globally.

Requested changes:

Request #1

Subject: Adverse Events Connected with the Neutrogena Visibly Clear Light Therapy Acne Mask

As it is not the adverse events that has driven us to approach regulators globally, but more the identification of a theoretical risk to a small subset of the population with underlying ocular conditions, resulted in the field action. Could we change the subject title to:

Subject: Field action for the Neutrogena® Visibly Clear® Light Therapy Acne Mask and Activator

Request #2

Current wording

Reason for Recall	Johnson & Johnson Pacific are advising that they have received reports, globally, pertaining to: 1. Distorted colour vision and/or blurred vision due to tearing; 2. Temporary loss of hue perception in blue spectrum; 3. Eye pain or irritation; and/or 4. Seeing spots or flashes. For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or lead to permanent vision loss.

Proposed Wording

Reason for Recall	Johnson & Johnson Pacific have advised that following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, J&J further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye. J&J identified that for a small subset of the population with certain underlying eye conditions (such as r*etinitis pigmentosa, ocular albinism or other hereditary ocular disorders*) or users taking medications which could enhance ocular photosensitivity, there exists a theoretical potential risk of be varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision This recall is being conducted as a precautionary measure. JJP has advised that this generation of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator are being withdrawn from the market and will no longer be supplied.

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Friday, 12 July 2019 10:06 AM
To: [redacted][JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted][JJPAU] <[redacted]@ITS.JNJ.com>; [redacted][CONAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] Sponsor Agreement Letter - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Please find attached a copy of the TGA's assessment for the proposed recall.

The text of the customer letter is acceptable **with the track changes in the attached document** and may be distributed to affected customers immediately.

Please forward a signed copy of the final letter to recalls@health.gov.au **by 12:00pm, Monday 16th July 2019.**

Note:
- When providing information about recalls to the TGA, please do not provide the names of individual patients.
- The TGA collects personal information about surgeons/healthcare professionals so that it can contact them about recalls and actions related to recalls.
- This collection is authorised under Australian Privacy Principle 3.6(b), Schedule 1 of the *Privacy Act 1998*. For general privacy information, go to Privacy information in the TGA website.

Please confirm receipt of this email.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

[redacted]
Johnson & Johnson Pacific Pty Ltd
45 Jones Street
Ultimo NSW 2007

By Email: [redacted]@its.jnj.com

12/07/2019

Our Ref: RC-2019-RN-00986-1

Dear [redacted]

Subject: Adverse Events Connected with the Neutrogena Visibly Clear Light Therapy Acne Mask

NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator (as a kit)

Neutrogena Visibly Clear Light Therapy Acne Mask
SAP Code: 26202031

Neutrogena Visibly Clear Light Therapy Acne Mask Activator
SAP Codes: 26202032 and 26202034

ARTG: 287825 - Johnson & Johnson Pacific Pty Ltd - Red/blue light phototherapy unit

Thank you for your notification of the above mentioned subject.

Pursuant to the current URPTG, this recall action has been classified as per the below summary:

Hazard Classification:	**Class II**
Type of Recall:	**Urgent Medical Device Recall**
Recall Level:	**Consumer**
Reason for Recall:	**Johnson & Johnson Pacific (JJP) have advised that following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, J&J further evaluated the potential effects of the NEUTROGENA Visibly Clear Light Therapy Acne Mask on the eye.** **JJP identified that for a small subset of the population with certain underlying eye conditions (such as retinitis pigmentosa, ocular albinism or other hereditary ocular disorders) or users taking medications which could enhance ocular photosensitivity, there exists a theoretical potential risk of be varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision**

	JJP has advised that this generation of the NEUTROGENA Visibly Clear Light Therapy Acne Mask and NEUTROGENA Visibly Clear Light Therapy Activator are being withdrawn from the market and will no longer be supplied.
Product Distribution:	**47 wholesalers, distributors and other organisations in NSW, QLD, SA, TAS, VIC and WA**
Customer Actions:	**Wholesalers:** **Johnson & Johnson Pacific is advising wholesalers to consolidate affected stock (in warehouse and from retailers) and raise a credit claim. Following processing of the credit claim, Johnson & Johnson Pacific Customer Service will contact facilities to provide a return number and pick up instructions.** **Retailers:** **Johnson & Johnson Pacific is advising retailers to contact their wholesaler to arrange credit and return of affected devices. Retailers should direct all consumer returns to the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a credit.** **Consumers:** **Consumers are advised to return their stock to the place of purchase for a full refund; or** **Contact Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a suitable refund.** **For further advice please see: [TGA WEBSTATEMENT LINK – TBC]**

Proposed recall action correspondence:

- The strategy for this recall action is acceptable;
- The text of the Customer Letter and Acknowledgement Form are both acceptable following implementation of the tracked changes in the attached documents, after-which they may be sent immediately; and
- A suitable consumer communication strategy including the draft 'Print Media Advertisement', as per the URPTG is yet to be agreed and finalised.

The above information will be broadcast to the various state and territory recall coordinators for therapeutic goods. Additionally, this information will be published in the public domain via the TGAs searchable database, System for Australian Recall Actions (SARA).

Both the recall broadcast and SARA publication will occur on the second clear business day following this date of this agreement letter.

Please note:

1. **Addressing of Recall Letters** - Recall correspondence is to be addressed in accordance with pages 48-49 of the 2017 URPTG. A sample is given of page 54. In particular, where hospitals are involved, letters should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable on a case-by-case basis.

2. Dispatch of Recall Letters – Recall Action letters are required to be dispatched to affected customers within 2 clear working days of receiving this agreement letter.

Recall envelopes as described on page 52 of the URPTG must be used where mail distribution is the chosen method of communication. It is also acceptable to dispatch this notification electronically (facsimile or email) subject to the ability to confirm receipt. If the Recall Action letter is dispatched via email, the subject line must reflect the appropriate title of the letter submitted, e.g. URGENT MEDICINE RECALL/URGENT PRODUCT DEFECT CORRECTION, followed by the name of the affected product.

Please advise the TGA if you are not able to initiate this Recall Action within 2 working days.

3. **Recall Actions for Consumer Goods that are also Therapeutic Goods** – When a therapeutic good is also a consumer good, the person carrying out the recall is required under the *Competition and Consumer Act 2010* (Schedule 2, Section 128 *'Notification requirements for a voluntary recall of consumer goods'*) to provide the Minister for Consumer Safety, written notification within 2 days after commencing the Recall Action. This can be done via the instructions outlined in Attachment 1 which also contains the URPTG definition of a Consumer Therapeutic Good.

4. Progress Reporting Requirements - In accordance with the responsibilities of sponsors (Step 10) in the URPTG, there is a requirement to submit a total of **three reports on the progress of the Recall Action as per the dates given in the table below. Typically these are at two weeks, six weeks and a 12 week close out report after the date of this correspondence**. An alternate timeframe or additional reports may be agreed on a case-by-case basis. Templates are given in Attachment 2 and this represents the minimum information expected, alternatively a suitable email will suffice. In the event all actions are completed prior to the specified dates given below, the report may be submitted earlier.

Report type:	**2 week**	**6 week**	**Close out**
Latest Due Date:	**26 July 2019**	**23 August 2019**	**14 October 2019**

5. TBS Update – As part of conducting this recall action, Sponsors are requested to verify that the relevant staff contact details given in the TBS Portal are up to date as per the guidance given in this link: https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators

Should you require any additional advice or further assistance with this recall, do not hesitate to contact me directly.

Yours sincerely,

[redacted]
Recalls Section
Manufacturing Quality Branch

Phone [redacted]
Email: recalls@health.gov.au

(Signed electronically)

Attachment 1:

NOTIFICATION OF A CONSUMER GOOD RECALL ACTION TO THE ACCC

Pursuant to subsection (7) of Section 128 of the *Competition and Consumer Act 2010.*

As per page 73 of the 2017 *Uniform Recall Procedure for Therapeutic Goods* (URPTG), this recall action is to be reported to the ACCC, if the product involved is a *therapeutic good* and also a *consumer good.*

The definition of consumer goods from the Australian Consumer Law is "… *goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption…"*

To make a report to the ACCC for a recall of a good that is both a therapeutic good and a consumer good, complete and submit the webform on the ACCC website by clicking on the link below:
https://www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall

General information regarding ACCC recalls may be obtained here:
https://www.productsafety.gov.au/recalls/guidance-for-suppliers/conducting-a-recall

Should you need further assistance in determining whether or not your *therapeutic good* is also a *consumer good*, please contact the ACCC directly by:

- Emailing the ACCC Recalls inbox Recalls@accc.gov.au

or

- Phoning the ACCC Recalls Hotline on: (02) 6243 1262

In the event you have doubt as to the status of your product in view of the above, **please do not report this action to the ACCC** unless the above determination has clearly been made and the product fits the definition of a *consumer good.*

Australian Government
Department of Health
Therapeutic Goods Administration

Attachment 2: Reporting Requirements

Reports should be submitted electronically to the Recalls Section via:

Email: recalls@health.gov.au

Please include the relevant TGA Recall reference number in the email subject line – e.g. RC-XXXX-RN-XXXXX-X

2 WEEK REPORT REQUIREMENTS:

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	**[ ] YES**	**[ ] NO.** Please explain:
2. Has a signed copy of the customer letter been provided to TGA Recalls?	**[ ] YES**	**[ ] NO.** Please ensure a signed copy of the letter is provided.
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain:
4. Have the initial investigation findings changed the scope of the recall/correction e.g. Additional units or products have not been identified with the same defect	**[ ] NO**	**[ ] YES.** Please advise:
5. For any product exported from Australia, has the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. Please list countries product has been exported to.	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain:

6 WEEK REPORTING REQUIREMENTS:

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded …….% And; <u>Detail attempts made to contact non-responding customers:</u>
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES** **[ ] No goods left to recall or correct.**	**[ ] NO.** Please advise when this is expected to occur:
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please detail:

3 MONTH CLOSE OUT REPORTING REQUIREMENTS (or by the previously agreed time):

1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or **(b) Correction - Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** *A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur: Please provide a list of non-responding customers:
2. What was the root cause of the defect that led to the recall/corrective action?	Please detail:	
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	Please detail:	
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% And; Detail attempts made to contact remaining customers

From: [redacted] [JJPAU]
To: Recalls
Cc: [redacted] [JJPAU]
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Tuesday, 16 July 2019 8:59:25 AM
Attachments: D19-5777610 Web Statement - Recall - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - JJP comment.docx

---

Hi [redacted]

Thanks for giving us the opportunity to review. I have attached a marked up version of the web statement and included some comments (we have 5 comments). More details around the comments are provided below.

I would be happy to talk to all of these comments with you over the phone - so if you could give me a call when you are in the office [redacted] I will talk you through these. Our intent has not been to change the style or the messaging.

JJP Comment #1

Request Potential is changed to theoretical

We would like to request the term "Potential" is changed to "Theoretical". Potential is showing the capacity to develop into something in the future (proven). Whilst Theoretical is conceptual (not-proven).

As per our HHE, there are no reports in the company safety data base of this There are no reports in the company's global safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users.

We also request the TGA to consider adding the following statement to the end of paragraph 4:

"Within Johnson & Johnson database we do not have any adverse events related to these potential risk conditions"

JJP Comment #2

The following comments are being made to ensure there is no unwarranted panic amongst consumers and to provide sufficient information to HCPs so they are aware of the conditions of the hypothetical susceptible population. The proposed changes are tracked, but I have highlighted in the paragraph below. The changes also ensure consistency across all messaging currently aligned.

For a small subset of potentially susceptible people (including people with enhanced light sensitivity or certain eye-related disorders e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders), repeated exposure may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss. Within Johnson & Johnson database we do not have any adverse events related to these potential risk

conditions

JJP Comment #3
We propose the addition of the words “mild and transient” to the paragraph describing the adverse events. This is again to reflect the nature of the AEs that could be experienced, but also to reduce the potential for consumer panic and alarm

JJP Comment #4
All therapeutic products have the potential for misuse and off label use. As an organisation this is not something we condone or promote.

We are very concerned that highlighting the issue of device modification or hacking the activator, it will drive unwanted behaviours amongst the users.

We have tried to design a simple and easy way for consumers to receive a refund, we hope that this will drive consumers to return the device and provide details of any AEs experienced rather than look for unapproved methods of device modification.

JJP Comment #5
We have made some minor changes to this paragraph. It is not our intent to change the meaning or the process here. Our requests here, are as follows:

1. Include the term “Consumers in Australia”. As you are aware, this is a global field action initiated by J&J. The Australian field action is different to all other markets and is the only market were product is actively being retrieved from consumers. The information here is specific for consumers in Australia. Websites are generally not geographically limited (unless specifically designed to). It is our understanding that there is no “geotagging” of the TGA website.
2. We are trying to encourage consumers to use the online portal to obtain their refunds rather than encouraging consumers to return this to their place of purchase – which always remains an option, however this approach has been taken to reduce the burden on retailers.

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 15 July 2019 4:53 PM
To [redacted][JJPAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

This is acceptable.

Please note – This web-statement was generated after TGA MO and TGA Communications Team Review.
The TGA will consider all suggested changes relating to technical issues and any errors of fact.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
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From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Monday, 15 July 2019 4:43 PM
To: Recalls
Subject: RE: DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

We have been circulating this internally, and I am going to need to send this up to my global colleagues for comment – Especially given the paragraph about the misuse and the potential device personalisation.

I will receive feedback overnight – so if we could hold until 9 am tomorrow morning, I would be most grateful

Thanks for your understanding

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 15 July 2019 1:21 PM
To [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] DRAFT TGA Web Statement - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Please find attached the TGA's draft web statement regarding the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator.

Could you please check for technical issues and to ensure accuracy and provide the TGA feedback by **COB TODAY 15th JULY 2019.**

Please note that this statement is aimed at both consumers and health professionals.

The TGA will consider all suggested changes relating to technical issues and any errors of fact.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Recall – ~~Potential~~ Theoretical fFor Eye Damage

Consumers and health professionals are advised that Johnson & Johnson Pacific, in consultation with the TGA, is recalling Neutrogena Visibly Clear Light Therapy Acne Mask and Activator. The device is also being withdrawn from the market.

Neutrogena Visibly Clear Light Therapy Acne Mask and Activator is a reusable non-sterile device, intended for home-use to treat mild to moderate acne on the face. The device comprises an 'acne face mask' and detachable corded 'activator'. It delivers a combination of red and blue light via light-emitting diodes (LEDs).

The activator is a small hand-held battery pack that is electronically limited to 30 sessions of 10 minutes each, ~~(one session~~intended to be used once per day~~)~~, after which it times out and a new one is to be purchased separately and the mask is re-used.

~~It has been identified that,~~ ~~F~~for a small subset of potentially susceptible people (including people with enhanced light sensitivity or certain eye-related disorders e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders)), repeated exposure may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss. Within Johnson & Johnson database we do not have any adverse events related to these potential risk conditions.

Commented [redacted]: Please add a link to the 'About recall actions' webpage http://www.tga.gov.au/safety/recalls-about.htm in a 'Related information' box.

Commented [redacted]2]: JJP #1
Request "potential" is changed to theoretical

Commented [redacted]: Hover text – The permanent removal of an affected therapeutic good from supply or use in the market.

Commented [redacted]4]: This is stated in the IFU but not electronically programmed into the activator. – remove this?

Commented [redacted]5]: Hover text - The retina is the sensory membrane that lines the inner surface of the back of the eyeball.

Commented [redacted]6]: JJP Comment #2
Added some wording to reduce the potential for consumer panic and also added examples of the conditions which might be susceptible to the theoretical risk identified. We believe this is useful for HCPs and consumers

Formatted: Highlight

~~Other~~ ~~p~~Potential mild transient adverse events that may be associated with use of this device are eye pain, eye discomfort, eye irritation, tearing, blinding, blurring of vision, seeing spots/flashes and other~~s~~ changes in vision (for example vision colour).

Commented [7]: JJP Comment #3
Added the word mild and transient to prevent alarm amongst consumers

~~It has also been identified that there foreseeable misuse, including the user staring directly at the LEDs and/or modifying the device so it can be used more longer than once per day10 minutes per session or on more than 30 occasions, increases the risk of serious adverse events.~~

Commented [8]: JJP comment #4
Recommendation is to delete this paragraph so as not to drive unwanted behaviours of device modificaiton

Information for consumers

Consumers in Australia using ~~If you or someone you provide care for uses~~ the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator, are advised to stop using the device and ~~return it to the place of purchase for a refund.~~

contact the Johnson & Johnson Pacific Consumer Care Centre by emailing neutrogenamaskAU@its.jnj.com or on 1800 789 348 to arrange return of the device and a refund. If you have any questions or concerns about the above issue, talk to your health professional.

Commented [9]: JJP Comment #5
Specific to Australia so the messages understand this is related to Australian consumers

Information for health professionals

If you are treating a patient who uses Neutrogena Visibly Clear Light Therapy Acne Mask and Activator, inform them of this issue and advise them ~~accordingly. Advise them~~ to cease using the device immediately and to report any adverse effects. ~~return the device to the place of purchase for a refund.~~

Commented [10]: That is commercial instruction that is not up to a medical practitioner to advise. (Is covered off in the consumer advice)

If you have any questions about this issue, contact Johnson & Johnson Pacific on 1800 789 348~~[phone number].~~

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices. Your report will contribute to the TGA's monitoring of these products. For more information, see the TGA Incident Reporting and Investigation Scheme (IRIS).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

From: Recalls
To: [redacted] [JJPAU]"
Cc: [redacted] [JJPAU]
Subject: RE: Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Monday, 15 July 2019 11:13:02 AM

Dear [redacted]

The Retail and Wholesale letters are approved for immediate release.

The consumer level communication strategy and the consumer recall notice (black triangle) is being reviewed by our medical officers.

A TGA Web-statement will be edited by our MOs and sent to you for review once it is completed.

If any further information is needed for these processes I will contact you.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Monday, 15 July 2019 9:59 AM
To: Recalls
Cc: [redacted] [JJPAU]
Subject: Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Please find attached the final retail and wholesale letters – there were a few minor tweaks requested by our global team – Nothing that really changes the intent of the letter (all changes

tracked)

I would also like to provide you with a draft version of the recall notice and also our intended social post for your review.

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Friday, 12 July 2019 10:06 AM
To: [redacted][JJPAU] <[redacted]@its.jnj.com>
Cc: [redacted][JJPAU] <[redacted]@its.jnj.com>; [redacted][CONAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] Sponsor Agreement Letter - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Please find attached a copy of the TGA's assessment for the proposed recall.

The text of the customer letter is acceptable **with the track changes in the attached document** and may be distributed to affected customers immediately.

Please forward a signed copy of the final letter to recalls@health.gov.au **by 12:00pm, Monday 16th July 2019.**

Note:
- When providing information about recalls to the TGA, please do not provide the names of individual patients.
- The TGA collects personal information about surgeons/healthcare professionals so that it can contact them about recalls and actions related to recalls.
- This collection is authorised under Australian Privacy Principle 3.6(b), Schedule 1 of the *Privacy Act 1998*. For general privacy information, go to Privacy information in the TGA website.

Please confirm receipt of this email.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

URGENT MEDICAL DEVICE RECALL

NEUTROGENA® VISIBLY CLEAR® LIGHT THERAPY ACNE MASK AND ACTIVATOR

ARTG ID: 287825

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), is recalling the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask (a battery powered mask worn by consumers that emits both red and blue light for the treatment of mild to moderate acne) and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator.

This action is being undertaken as a precautionary measure.

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the Mask on the eye.

It has been identified that there is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance the eye's sensitivity to light. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

In alignment with the recommendation of the TGA, if you have purchased these devices, please discontinue use.

To return the devices and obtain a refund contact the Johnson & Johnson Pacific Consumer Care Centre:

EMAIL: neutrogenamaskAU@its.jnj.com PHONE:1800 789 348

If you experience any adverse symptoms, you should contact your healthcare professional and report the incident at consumer@its.jnj.com.

Johnson & Johnson Pacific Pty Ltd sincerely regrets any inconvenience to their consumers.

Facebook and Instagram

Recall notice for consumers in Australia

You may have noticed that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator are not available where you shop in Australia. That's because these products have been recalled.

This action is being undertaken as a precautionary measure.

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the Mask on the eye.

It has been identified that there is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance the eye's sensitivity to light. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

In alignment with the recommendation of the TGA, if you have purchased these devices, please discontinue use.

To return the devices and obtain a refund, contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or neutrogenamaskAU@its.jnj.com.

If you experience any adverse symptoms, please contact your healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com.

Johnson & Johnson Pacific sincerely regrets any inconvenience to their consumers.

Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: [X] July 2019.

Dear [customer name],

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Customers are advised that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator are being withdrawn and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers in Australia should be advised to discontinue use and contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or neutrogenamaskAU@its.jnj.com to return the device and arrange for a refund.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com

Actions to be taken:

Our records show that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further distribution;
- Complete the **Recall Acknowledgement Form** (attached) immediately, whether you have affected medical devices or not and return the form to **CustomerService2@ITS.JNJ.COM** ;
- If the affected medical devices have been forwarded to a retail store, contact that retailer with the attached **Letter to Retailers** and the **Recall Acknowledgement Form**, which they need to fill in and return to you, whether they have affected medical devices or not;
- Before you raise a credit claim, please ensure you have collected all acknowledgement forms and affected devices from your retailers;
- Raise a credit claim in your system and email the claim and the consolidated Acknowledgement Forms to **CustomerService2@ITS.JNJ.COM;**

- Once the claim has been received, Johnson & Johnson Pacific Customer Service will contact you to provide your return number and pick up instructions.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products, which is why we have voluntarily initiated this process.

If you have any other questions, please don't hesitate to contact your business manager.

Yours sincerely

[redacted]
Johnson & Johnson Pacific

Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: X July 2019

Dear Retailer,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Retailers are advised that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator are being withdrawn and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers in Australia should be advised to discontinue use and contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or neutrogenamaskAU@its.jnj.com to return the device and arrange for a refund.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com

Actions to be taken:

We understand that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further distribution;
- Complete the **Recall Acknowledgement Form** (attached) immediately whether you have stock or not;
- Return the acknowledgement form with your existing inventory to the wholesaler you obtained it from and arrange for a credit;
- Please direct all consumer returns to the Johnson & Johnson Pacific Consumer Care Centre at neutrogenamaskAU@its.jnj.com to organise the return of all affected devices and arrange a refund.
- Place this letter in a prominent position for at least one month.

Ensure relevant staff members are informed of this recall.

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing a copy of this letter and the Recall Acknowledgment Form.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products which is why we have voluntarily initiated this action.

Yours sincerely

[redacted]
[redacted]
Johnson & Johnson Pacific

Australian Government
Department of Health
Therapeutic Goods Administration

[redacted]
Johnson & Johnson Pacific Pty Ltd
45 Jones Street
Ultimo NSW 2007

By Email: [redacted]@its.jnj.com

12/07/2019

Our Ref: RC-2019-RN-00986-1

Dear [redacted]

Subject: Adverse Events Connected with the Neutrogena Visibly Clear Light Therapy Acne Mask

NEUTROGENA Visibly Clear Light Therapy Acne Mask and Activator (as a kit)

Neutrogena Visibly Clear Light Therapy Acne Mask
SAP Code: 26202031

Neutrogena Visibly Clear Light Therapy Acne Mask Activator
SAP Codes: 26202032 and 26202034

ARTG: 287825 - Johnson & Johnson Pacific Pty Ltd - Red/blue light phototherapy unit

Thank you for your notification of the above mentioned subject.

Pursuant to the current URPTG, this recall action has been classified as per the below summary:

Hazard Classification:	**Class II**
Type of Recall:	**Urgent Medical Device Recall**
Recall Level:	**Consumer**
Reason for Recall:	**Johnson & Johnson Pacific are advising that they have received reports, globally, pertaining to:** **1. Distorted colour vision and/or blurred vision due to tearing;** **2. Temporary loss of hue perception in blue spectrum;** **3. Eye pain or irritation; and/or** **4. Seeing spots or flashes.** **For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision**

	impairment or lead to permanent vision loss.
Product Distribution:	[redacted]
Customer Actions:	**<u>Wholesalers:</u>** **Johnson & Johnson Pacific is advising wholesalers to consolidate affected stock (in warehouse and from retailers) and raise a credit claim. Following processing of the credit claim, Johnson & Johnson Pacific Customer Service will contact facilities to provide a return number and pick up instructions.** **<u>Retailers:</u>** **Johnson & Johnson Pacific is advising retailers to contact their wholesaler to arrange credit and return of affected devices. Retailers should direct all consumer returns to the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a credit.** **<u>Consumers:</u>** **Consumers are advised to return their stock to the place of purchase for a full refund; or** **Contact Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a suitable refund.**

Proposed recall action correspondence:

- The strategy for this recall action is acceptable;
- The text of the Customer Letter and Acknowledgement Form are both acceptable following implementation of the tracked changes in the attached documents, after-which they may be sent immediately; and
- A suitable consumer communication strategy including the draft 'Print Media Advertisement', as per the URPTG is yet to be agreed and finalised.

The above information will be broadcast to the various state and territory recall coordinators for therapeutic goods. Additionally, this information will be published in the public domain via the TGAs searchable database, System for Australian Recall Actions (SARA).

Both the recall broadcast and SARA publication will occur on the second clear business day following this date of this agreement letter.

Please note:
1. Addressing of Recall Letters - Recall correspondence is to be addressed in accordance with pages 48-49 of the 2017 URPTG. A sample is given of page 54. In particular, where hospitals are involved, letters should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable on a case-by-case basis.

2. Dispatch of Recall Letters – Recall Action letters are required to be dispatched to affected customers within 2 clear working days of receiving this agreement letter.

Recall envelopes as described on page 52 of the URPTG must be used where mail distribution is the chosen method of communication. It is also acceptable to dispatch this notification electronically (facsimile or email) subject to the ability to confirm receipt. If the Recall Action letter is dispatched via email, the subject line must reflect the appropriate title of the letter submitted, e.g. URGENT MEDICINE RECALL/URGENT PRODUCT DEFECT CORRECTION, followed by the name of the affected product.

Please advise the TGA if you are not able to initiate this Recall Action within 2 working days.

3. **Recall Actions for Consumer Goods that are also Therapeutic Goods** – When a therapeutic good is also a consumer good, the person carrying out the recall is required under the *Competition and Consumer Act 2010* (Schedule 2, Section 128 *'Notification requirements for a voluntary recall of consumer goods'*) to provide the Minister for Consumer Safety, written notification within 2 days after commencing the Recall Action. This can be done via the instructions outlined in Attachment 1 which also contains the URPTG definition of a Consumer Therapeutic Good.

4. Progress Reporting Requirements - In accordance with the responsibilities of sponsors (Step 10) in the URPTG, there is a requirement to submit a total of **three reports on the progress of the Recall Action as per the dates given in the table below. Typically these are at two weeks, six weeks and a 12 week close out report after the date of this correspondence**. An alternate timeframe or additional reports may be agreed on a case-by-case basis. Templates are given in Attachment 2 and this represents the minimum information expected, alternatively a suitable email will suffice. In the event all actions are completed prior to the specified dates given below, the report may be submitted earlier.

Report type:	**2 week**	**6 week**	**Close out**
Latest Due Date:	**26 July 2019**	**23 August 2019**	**14 October 2019**

5. TBS Update – As part of conducting this recall action, Sponsors are requested to verify that the relevant staff contact details given in the TBS Portal are up to date as per the guidance given in this link: https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators

Should you require any additional advice or further assistance with this recall, do not hesitate to contact me directly.

Yours sincerely,

[redacted]
Recalls Section
Manufacturing Quality Branch

Phone [redacted]
Email: recalls@health.gov.au

(Signed electronically)

Attachment 1:

NOTIFICATION OF A CONSUMER GOOD RECALL ACTION TO THE ACCC

Pursuant to subsection (7) of Section 128 of the *Competition and Consumer Act 2010.*

As per page 73 of the 2017 *Uniform Recall Procedure for Therapeutic Goods* (URPTG), this recall action is to be reported to the ACCC, if the product involved is a *therapeutic good* and also a *consumer good.*

The definition of consumer goods from the Australian Consumer Law is "… *goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption…"*

To make a report to the ACCC for a recall of a good that is both a therapeutic good and a consumer good, complete and submit the webform on the ACCC website by clicking on the link below:
https://www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall

General information regarding ACCC recalls may be obtained here:
https://www.productsafety.gov.au/recalls/guidance-for-suppliers/conducting-a-recall

Should you need further assistance in determining whether or not your *therapeutic good* is also a *consumer good*, please contact the ACCC directly by:

- Emailing the ACCC Recalls inbox Recalls@accc.gov.au

or

- Phoning the ACCC Recalls Hotline on: (02) 6243 1262

In the event you have doubt as to the status of your product in view of the above, **please do not report this action to the ACCC** unless the above determination has clearly been made and the product fits the definition of a *consumer good.*

Australian Government
Department of Health
Therapeutic Goods Administration

Attachment 2: Reporting Requirements

Reports should be submitted electronically to the Recalls Section via:

Email: recalls@health.gov.au

Please include the relevant TGA Recall reference number in the email subject line – e.g. RC-XXXX-RN-XXXXX-X

2 WEEK REPORT REQUIREMENTS:

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	**[ ] YES**	**[ ] NO.** Please explain:
2. Has a signed copy of the customer letter been provided to TGA Recalls?	**[ ] YES**	**[ ] NO.** Please ensure a signed copy of the letter is provided.
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain:
4. Have the initial investigation findings changed the scope of the recall/correction e.g. Additional units or products have not been identified with the same defect	**[ ] NO**	**[ ] YES.** Please advise:
5. For any product exported from Australia, has the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. Please list countries product has been exported to.	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain:

6 WEEK REPORTING REQUIREMENTS:

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded …….% And; <u>Detail attempts made to contact non-responding customers:</u>
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES** **[ ] No goods left to recall or correct.**	**[ ] NO.** Please advise when this is expected to occur:
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please detail:

3 MONTH CLOSE OUT REPORTING REQUIREMENTS (or by the previously agreed time):

1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or **(b) Correction - Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** *A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur: Please provide a list of non-responding customers:
2. What was the root cause of the defect that led to the recall/corrective action?	Please detail:	
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	Please detail:	
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% And; Detail attempts made to contact remaining customers

Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask

and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator

AFFECTED DEVICES:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

On behalf of this organisation I acknowledge receipt of the Medical Device Recall notice date Wednesday 10th July 2019 relating to the above product.

FROM:

Organisation	~~Johnsons & Johnson Pacific Pty Ltd (EID 786)~~
Position	[redacted]
Name	[redacted]
Email or fax no.	[redacted]~~@its.jnj.com~~
Telephone no.	[redacted]
Date	~~10th July 2019~~
Signature	

Commented [redacted]: Assuming this information is for the customer to fill out

Affected Stock

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	**Batch/Lot/Date**	**Quantity of stock received**	**Quantity of unused stock subject to recall (currently in quarantine)**
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator			
Neutrogena Visibly Clear Light Therapy Acne Mask Activator			
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Name	[redacted]
Position	[redacted]
Organisation	Johnson & Johnson Pacific
Address	45 Jones Street, Ultimo NSW 2007
Email	[redacted]@its.jnj.com
Subject of email	Neutrogena Visibly Clear Light Therapy Acne Mask and Activator
Telephone no.	1800 638 047 (press '2')

~~**DRAFT LETTER TO RETAIL STORES**~~

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

Formatted: Font: 10 pt, Not Bold, No underline

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: X July 2019

Dear Retailer,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment; consumers can continue to use the Spot Treatment as directed.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

~~Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient.~~

Commented [ ]: Already stated in first paragraph

There is a theoretical potential risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this -small subset of individuals with the underlying eye conditions.

This recall is being conducted ~~out of an abundance of caution.~~as a precautionary measure. Customers are advised that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator is being withdrawn from the market and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers in Australia should be advised to discontinue use and return the devices to the place of purchase or contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or [email address TBA] for a refund.

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If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com

Actions to be taken:

We understand that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further use;
- Complete the **Recall Acknowledgement Form** (attached) immediately whether you have stock or not;
- Return the acknowledgement form with your existing inventory to your wholesaler and arrange for a credit;

Johnson & Johnson Pacific

- Please direct all consumer returns to the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 to organise the return of all affected devices and arrange a credit.
- Place this letter in a prominent position for at least one month.

Ensure relevant staff members are informed of this recall.

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing a copy of this letter.

~~Place this letter in a prominent position for at least one month.~~

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products which is why we have voluntarily initiated this action.

Yours sincerely

[redacted]
Johnson & Johnson Pacific

~~DRAFT LETTER TO WHOLESALERS~~

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

Formatted: Font: 9 pt, Not Bold, No underline

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: [X] 2019.

Dear [customer name],

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment.

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

~~Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient.~~

Commented [1]: Already mentioned in first paragraph

There is a theoretical potential risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Customers are further advised that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator is being withdrawn from the market and will no longer be supplied.~~This recall is being conducted out of an abundance of caution.~~

In alignment with the recommendation of the TGA, consumers in Australia should be advised to discontinue use and return the devices to the place of purchase or contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or [email address TBA] for a refund.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com

Actions to be taken:

Our records show that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further use;
- Complete the **Recall Acknowledgement Form** (attached) immediately, whether you have affected medical devices or not and return the form to [redacted]**@its.jnj.com**;
- If the affected medical devices have been forwarded to a retail store, contact that retailer with the attached **Letter to Retailers** and the **Recall Acknowledgement Form**,

which they need to fill in and return to you, whether they have affected medical devices or not;

- Before you raise a credit claim, please ensure you have collected all acknowledgement forms and affected devices from your retailers;
- Raise a credit claim in your system and email the claim and the consolidated Acknowledgement Forms to [redacted] at [redacted]**@its.jnj.com;**
- Once the claim has been processed, Johnson & Johnson Pacific Customer Service will contact you to provide your return number and pick up instructions.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products, which is why we have voluntarily initiated this process. If you have any other questions, please don't hesitate to contact your business manager.

Yours sincerely

[redacted]
[redacted]
Johnson & Johnson Pacific

From: [redacted] [JJPAU]
To: Recalls
Cc: [redacted] [JJPAU]
Subject: Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 12 July 2019 5:22:33 PM
Attachments: Sponsor Consumer Level Communication Strategy.docx
ATT00001.htm

Dear [redacted]

Please find attached a copy of our proposed communications strategy.

We are very happy to have further conversations about the strategy should you feel the need

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

OVERVIEW & KEY MESSAGES

- **Description of product**:
  The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask (Starter Kit, Model 31000) is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of red and blue light via light-emitting diodes (LEDs), and weighs less than 400g.

  The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator (Model 71000) is offered separately to increase the number of doses available from the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries.

- **Description of Issue**:
  As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

  Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient.

  There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

  Description of Health Risks:
  For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk that varying degrees of peripheral retinal damage could occur.

- **Description of Consumer Actions to be Taken**:
  Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration, is recalling the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator. This action is being taken as a precautionary measure.

  In alignment with the recommendation of the TGA, Consumers in Australia who have purchased the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator should discontinue use.

  Consumers can return the devices by contacting the Johnson & Johnson Pacific Consumer Care Centre at neutrogenamaskAU@its.jnj.com or 1800 789 348

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

- **Contact Information for Consumers**:
  Email Johnson & Johnson Pacific Consumer Care Centre at neutrogenamaskAU@its.jnj.com for refunds and returns
  Phone Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348

  Consumers experiencing any adverse symptoms should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com.

- **Method of Product Recovery, Disposal or Correction:**
  If consumers have purchased the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator, they should contact the Johnson & Johnson Pacific Consumer Care Centre via email neutrogenamaskAU@its.jnj.com or call 1800 789 348 to arrange the return of devices and obtain refund.

  Johnson & Johnson Pacific (JJP) will arrange for the destruction of all devices with a suitable environmentally friendly disposal vendor.

  A decision has been made to globally discontinue the current generation of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask due to the fact the product underperformed commercially.

COMMUNICATIONS OBJECTIVES

- **Communications objectives**:
  - To ensure consumers who have purchased the devices are aware of the field action, know how to return the devices and obtain a refund
  - To ensure retailers know how to return the devices and obtain a credit from their wholesaler
  - To ensure wholesalers know how to return the devices and obtain a credit from JJP

- **Estimated Outcome (including timeframe):**
  A recall effectiveness at the wholesaler level of 90% is anticipated. JJP does not have visibility of the complete list of retailers that are part of each wholesaler's network. Wholesalers will be required with to contact all of their retailers and provide:
  - Number of retailers successfully contacted that received a complete recall package via returned acknowledgement forms
  - Total number of units at retailer's inventory at the time of notification
  - Total number of units returned to wholesaler by each retailer.

  Since activators are disposable, we anticipate that customers will have only on hand the ones they are using. For both the mask and the activators we are providing incentive to return them in the form of a refund.

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

COMMUNICATIONS ASSETS TO BE PRODUCED (To be confirmed upon review and approval by TGA)

- TGA Recall Notice (black box) – [file name]
- Neutrogena website post (for product page) – [file name]
- Wholesaler letter – [file name]
- Retailer letter – [file name]
- Recall acknowledgement form – [file name]
- Social media post – [file name]
- Internal communications for field team – [file name]
- Industry association letter – [file name]
- Consumer letter – [file name]

KEY TIMINGS

Dates are indicative only. Final dates to be agreed following final consultation with TGA

- Action: Communications to be finalised in consultation with TGA by Monday 15 July 2019
- Action: JJP field team to be briefed on Tuesday 16 July 2019
- Action: Phone calls with wholesaler customers followed by wholesaler letters, retailer letters and acknowledgement forms to be emailed to customers to commence on Tuesday 16 July 2019
- Action: Refunds website to be live Wednesday 17 July 2019
- Action: Social and website posts to be uploaded on Wednesday 17 July 2019
- Action: Industry groups to be notified on Wednesday 17 July 2019

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

RATIONALE FOR CONSUMER CHANNEL SELECTION

The core audience for the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is females aged 16-35. This demographic over-indexes against digital, including social media. This, along with market intelligence on audience media behaviours, has informed the decision to invest almost 100% of marketing spend in digital channels since the mask was launched in August 2017.

The average monthly sales to consumers are approximately [redacted] units of the mask and [redacted] activators. Each activator contains 30 days use. **We therefore estimate that there only [redacted] masks currently in use**.

Our communications strategy is focused on using the most effective channels to reach our audience ie digital and social to target those who have purchased the mask, ensuring the highest chance of visibility to current users.

The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator is a [redacted] **roduct** in Australia. [redacted]

We propose to send a consumer letter through Chemist Warehouse and Priceline databases to all consumers who have purchased the devices via e-commerce or through their loyalty schemes, for example Priceline's "Sister Club". Please note that given we have not communicated this to Priceline or Chemist Warehouse, we need to confirm when and how this could be done.

A combination of Facebook and Instagram posts provides the most effective reach for our audience. Posts with information on the recall will be shown on Facebook and Instagram where 60% of this audience is.

A global decision has been made to display a recall notice on all Neutrogena websites in countries where the mask is sold.

Johnson & Johnson Pacific (JJP) Consumer-Level Recall
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator

Consumer Level Communications Strategy

12 July 2019

COMMUNICATIONS STAKEHOLDER TIMEFRAME MATRIX:

STAKEHOLDER	What/Action	Media outlet/channel	Signature	DATE
EXTERNAL				
Wholesalers	Send recall acknowledgement forms and retail letters to all retailers	Email	[Signature]	[Date Actionable]
Retailers	Wholesalers to send retail letters to all retailers	Email	[Signature]	[Date Actionable]
Priceline and Chemist Warehouse customers [redacted]	We will send the consumer letter through Chemist Warehouse and Priceline databases to all consumers who have purchased the devices through e-commerce or through their loyalty schemes, for example Priceline's "Sister Club".	Email	[Signature]	[Date Actionable]
All other e-retailers eg Amazon	Place consumer letter with information for consumers on e-commerce site	To be placed on ecommerce site	[Signature]	[Date Actionable]
Consumers	Social media post – copy plus recall notice	Neutrogena AU Facebook (5.2m followers) Neutrogena AU Instagram (8k followers)	[Signature]	[Date Actionable]
Consumers	Website post – TGA recall notice Website post – consumer website copy	Neutrogena.com.au – home page Neutrogena.com.au – product page	[Signature]	[Date Actionable]
TGA website	Website post - recall notice	TGA website	[Signature]	[Date Actionable]
GOV/INDUSTRY CONTACTS				
Consumer Health Products Australia	Industry association letter	Letter to be sent by email	[Signature]	[Date Actionable]
ACCORD	Industry association letter	Letter to be sent by email	[Signature]	[Date Actionable]
MTAA	Industry association letter	Letter to be sent by email	[Signature]	[Date Actionable]
INTERNAL				
All employees	Brief all employees	Face to face and phone calls	[Signature]	[Date Actionable]
Internal field and HCP teams	Brief the field and HCP teams	Phone call to be followed up with email with wholesaler letter, retailer letter, recall acknowledgement form	[Signature]	[Date Actionable]
Consumer Care Centre	Brief the CCC team	Phone call	[Signature]	[Date Actionable]
Staff shops	Complete retailer recall process	In store	[Signature]	[Date Actionable]

From: Recalls
To: [redacted][JJPAU]"
Subject: RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 12 July 2019 9:58:56 AM

Hi [redacted]

No problems for the call time change. Thank you for the prompt response.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Friday, 12 July 2019 9:56 AM
To: Recalls
Subject: Re: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

I am just trying to find out availability of my Comms team lead - would you be open to moving the call until 2pm this afternoon ? (We were planning on sending to you this afternoon - just waiting on sign off...)

Kind regards

[redacted]
Sent from my iPhone

On 12 Jul 2019, at 09:48, Recalls <Recalls@health.gov.au> wrote:

Dear [redacted]

Regarding the consumer level communication strategy, some available options include:

- J & J Australia website statement
- J & J Social Media Posts
- Newspaper Advertisements (Black Triangle Template Attached)
- Professional Medical Colleges And Societies
- TGA will publish on their website
- TGA on their Facebook and twitter
- ACCC website (TGA notified)
- Primary Healthcare Network (DoH) (TGA notified)
- Pharmacy Guild (TGA notified)
- AMA (TGA notified)

Please provide an edited version of the Consumer Level Media Advertisement document (see attached) by COB Today 12/07/2019.

I will try and call you around 11am today to discuss your consumer level communication strategy.

By COB today you will have receive an Agreement Letter regarding this recall issue.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

<image001.jpg>

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Wednesday, 10 July 2019 4:20 PM
Subject: RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Please find attached information that has been pulled from our Product Quality Management System (PQMS) for the NTLAM (report Period July 2017 to present) – limited the AEs captured as either relating to visual disturbances, eye disorder and Neurological disorder for Australia

There are only 11 AEs in the report (1 appears to be a duplication), 9 relating to eye/visual disturbance received since launch and 1 relating to a neurological issue. Of these, **only one AE was assessed as serious**. This has been highlighted yellow in the attached spreadsheet and was the only one reported to the TGA with the Reference Number: 54651

Please do let me know if you need any further information.

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Wednesday, 10 July 2019 2:30 PM
To [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>; [redacted] [CONAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

I have tried calling your landline and mobile for a quick chat with no luck.

On reviewing our information – The HHE states:

Region	Reporting rate for eye reactions (per million units shipped)	CIOMS Classification	Reporting rate for neurologic disorders (per million units shipped)	CIOMS Classification
Asia Pacific	356.14	Rare	89.04	Very rare

Can you please confirm with me the number of adverse events that have been reported within Australia only.

Kind Regards,

[redacted]

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: Recalls [mailto:Recalls@health.gov.au]
Sent: Wednesday, 10 July 2019 1:28 PM
Subject: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank you for the letters. I have attached the TGA amended versions for your perusal.

We will await your communication strategy for consumer level products.

Kind Regards,

[redacted]

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]

Sent: Wednesday, 10 July 2019 12:13 PM
To: Recalls
Cc: [redacted] [JJPAU]; [redacted] [CONAU]; [redacted]
Subject: RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

We would like to thank the TGA for its understanding on Johnson & Johnson Pacific's (JJP's) request to extend the deadline to agree to the proposed recall action and provide the requested information.

Level and Class of Recall

We confirm that JJP will undertake the voluntary recall in line with the TGA's assessment that it be conducted as a Class II, consumer level recall.

That being said, JJP stands by its position that the appropriate course of action should be a Class III, retail level recall. Our assessment, as stated in the HHE, indicates that the risk of eye injury in a very small subset of the population is theoretical. Further, it is our assessment that:

- More than [redacted] units of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask (NLTAM) have been sold globally. Reports of visual effects associated with use of the device are rare, generally mild and transient. No pattern of major clinical concern was identified for these events and no serious adverse events were deemed causally related to the device.
- For a very small subset of the population with certain underlying eye conditions e.g. retinitis pigmentosa, ocular albinism or other congenital retinal disorders, there is a theoretical risk that varying degrees of peripheral retinal damage could occur.
- There are no reports in the company's global safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users.
- The TGA refer to the statement in the HHE that "*New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration*". When used as directed, peripheral regions of the retina might be illuminated. However, it is important to note that with the position of the lower LEDs on the device, the macula is not expected to have direct exposure to blue light and indirect illumination is not expected to affect the macula.
- The HHE reflects input from a number of independent experts who agreed that individuals with the underlying ocular conditions would have an increased sensitivity to light and are likely to feel significant discomfort if they did use the light mask. Consequently, it is almost certain they would not continue to use the product.

To date, regulators in other similar markets (Canada, US, Germany, France, Portugal and New Zealand) have aligned to a retail level recall without any consumer

communication. UK and Ireland have aligned to retail level recall, with minimal consumer communication.

Despite our different view on the appropriate classification and recall level, JJP will undertake the recall in line with the TGA's view.

Updated TGA Acknowledgement Form
As requested, I have provided the acknowledgement form as per the current URPTG.

Updated Customer List
The customer list previously provided to the TGA remains unchanged. For convenience, this list is provided again.

Updated Retailer & Wholesaler Letter
As you are aware, J&J is undertaking a voluntary recall in the markets listed above. Importantly the communications used in each of these markets are consistent. In light of this, we respectfully request that the TGA agree to JJP aligning the language used within our communications to Australian consumers, retailers and wholesalers with the communications in those other markets. We trust that the TGA will agree to this request given the TGA's view that the approach in both Australia and the UK are congruent.

We provide a copy of the field notice on the MHRA website for your reference.

With this email I am providing you with draft retailer and wholesaler letters. Our initial letters, that the TGA commented on, were prepared on the basis that we would be undertaking a retail level recall. Acknowledging that we will now be undertaking a consumer level recall, we have redrafted the letters to ensure they will be easy for the intended recipients to understand, as required by the URPTG.

TGA Recall Notice
As requested, I have provided the recall notice.

Communication Strategy
JJP is progressing this process and we propose providing a communications strategy following on from your alignment on the recall letters.

Next Steps by TGA
We would welcome your feedback in relation to the proposed recall steps. Please do not hesitate to contact me to discuss as needed.

Kind Regards

[redacted]
Pacific & North Asia

Johnson & Johnson Pacific
Locked Bag 5, BROADWAY NSW 2007 AUSTRALIA
45 Jones Street ULTIMO NSW 2007 AUSTRALIA
Tel: [redacted] | Mobile: [redacted]
Email: [redacted]@its.jnj.com

From: Recalls
Sent: Friday, 5 July 2019 2:57 PM
To: [redacted] [JJPAU]
Cc [redacted] [JJPAU] ; [redacted] [CONAU] ; [redacted]
Subject: [EXTERNAL] Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank you for the phone call.

It is noted that due to the American long weekend, the documents requested will be provided by Wednesday 10th July, 12pm.

Please see below a range of options for the communication strategy – i.e. publishing the Print media Advert with the black triangle:

- JNJ website statement;
- JNJ Social Media Statements;
- TGA will publish on our website;
- TGA on their Facebook and twitter;
- ACCC website (TGA notified);
- Primary Healthcare Network (DoH) (TGA notified);
- Combination of National and/or State newspapers; and

• Media Release by JNJ.

The Recalls team is experimenting with a new template for organising communication strategies for consumer level recalls.

Could you please populate this document with relevant information regarding your own consumer notification strategy and provide it ASAP.

If you need any help or wish to discuss this please feel free to give me a call.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

<image001.jpg>

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this

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<urptg-example-consumer-level-media-advertisement.docx>

<uniform-recall-procedure-therapeutic-goods-urptg.pdf>

From: Recalls
To: [redacted] [JJPAU]"
Cc: [redacted] [JJPAU]; [redacted] [CONAU]
Subject: Adverse Events - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Wednesday, 10 July 2019 4:34:53 PM

Dear [redacted]

Thank you for the phone calls and information.
This will help provide some clarity internally.

We will await the consumer communication strategy.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Wednesday, 10 July 2019 4:20 PM
To: Recalls
Cc: [redacted] [JJPAU]; [redacted] [CONAU]
Subject: RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Please find attached information that has been pulled from our [redacted] for the NTLAM (report Period July 2017 to present) – limited the AEs captured as either relating to visual disturbances, eye disorder and Neurological disorder for Australia

There are only 11 AEs in the report (1 appears to be a duplication), 9 relating to eye/visual disturbance received since launch and 1 relating to a neurological issue. Of these, **only one AE was assessed as serious**. This has been highlighted yellow in the attached spreadsheet and was

the only one reported to the TGA with the Reference Number: 54651

Please do let me know if you need any further information.

Kind regards

[redacted]

From: Recalls <Recalls@health.gov.au>
Sent: Wednesday, 10 July 2019 2:30 PM
To [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>; [redacted] [CONAU] <[redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

I have tried calling your landline and mobile for a quick chat with no luck.

On reviewing our information – The HHE states:

Region	Reporting rate for eye reactions (per million units shipped)	CIOMS Classification	Reporting rate for neurologic disorders (per million units shipped)	CIOMS Classification
Asia Pacific	356.14	Rare	89.04	Very rare

Can you please confirm with me the number of adverse events that have been reported within Australia only.

Kind Regards,

[redacted]

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

are met.

From: Recalls [mailto:Recalls@health.gov.au]
Sent: Wednesday, 10 July 2019 1:28 PM
Subject: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dea [redacted]

Thank you for the letters. I have attached the TGA amended versions for your perusal.

We will await your communication strategy for consumer level products.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Wednesday, 10 July 2019 12:13 PM
To: Recalls
Cc: [redacted] [JJPAU]; [redacted] [CONAU]; [redacted]
Subject: RE: Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

We would like to thank the TGA for its understanding on Johnson & Johnson Pacific's (JJP's) request to extend the deadline to agree to the proposed recall action and provide the requested information.

Level and Class of Recall

We confirm that JJP will undertake the voluntary recall in line with the TGA's assessment that it be conducted as a Class II, consumer level recall.

That being said, JJP stands by its position that the appropriate course of action should be a Class III, retail level recall. Our assessment, as stated in the HHE, indicates that the risk of eye injury in a very small subset of the population is theoretical. Further, it is our assessment that:

- More than [redacted] units of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask (NLTAM) have been sold globally. Reports of visual effects associated with use of the device are rare, generally mild and transient. No pattern of major clinical concern was identified for these events and no serious adverse events were deemed causally related to the device.
- For a very small subset of the population with certain underlying eye conditions e.g. retinitis pigmentosa, ocular albinism or other congenital retinal disorders, there is a theoretical risk that varying degrees of peripheral retinal damage could occur.
- There are no reports in the company's global safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users.
- The TGA refer to the statement in the HHE that "*New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration*". When used as directed, peripheral regions of the retina might be illuminated. However, it is important to note that with the position of the lower LEDs on the device, the macula is not expected to have direct exposure to blue light and indirect illumination is not expected to affect the macula.
- The HHE reflects input from a number of independent experts who agreed that individuals with the underlying ocular conditions would have an increased sensitivity to light and are likely to feel significant discomfort if they did use the light mask. Consequently, it is almost certain they would not continue to use the product.

To date, regulators in other similar markets (Canada, US, Germany, France, Portugal and New Zealand) have aligned to a retail level recall without any consumer communication. UK and Ireland have aligned to retail level recall, with minimal consumer communication.

Despite our different view on the appropriate classification and recall level, JJP will undertake the recall in line with the TGA's view.

Updated TGA Acknowledgement Form

As requested, I have provided the acknowledgement form as per the current URPTG.

Updated Customer List

The customer list previously provided to the TGA remains unchanged. For convenience, this list is provided again.

Updated Retailer & Wholesaler Letter

As you are aware, J&J is undertaking a voluntary recall in the markets listed above. Importantly the communications used in each of these markets are consistent. In light of this, we respectfully request that the TGA agree to JJP aligning the language used within our communications to

Australian consumers, retailers and wholesalers with the communications in those other markets. We trust that the TGA will agree to this request given the TGA's view that the approach in both Australia and the UK are congruent.

We provide a copy of the field notice on the MHRA website for your reference.

With this email I am providing you with draft retailer and wholesaler letters. Our initial letters, that the TGA commented on, were prepared on the basis that we would be undertaking a retail level recall. Acknowledging that we will now be undertaking a consumer level recall, we have redrafted the letters to ensure they will be easy for the intended recipients to understand, as required by the URPTG.

TGA Recall Notice
As requested, I have provided the recall notice.

Communication Strategy
JJP is progressing this process and we propose providing a communications strategy following on from your alignment on the recall letters.

Next Steps by TGA
We would welcome your feedback in relation to the proposed recall steps. Please do not hesitate to contact me to discuss as needed.

Kind Regards

[redacted]

[redacted]
Pacific & North Asia

Johnson & Johnson Pacific
Locked Bag 5, BROADWAY NSW 2007 AUSTRALIA
45 Jones Street ULTIMO NSW 2007 AUSTRALIA
Tel: [redacted] | Mobile: [redacted]
Email: [redacted]@its.jnj.com

From: Recalls
Sent: Friday, 5 July 2019 2:57 PM
To: [redacted] [JJPAU]
Cc: [redacted] [JJPAU] ; [redacted] [CONAU] [redacted]
Subject: [EXTERNAL] Sponsor Communication Strategy - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank you for the phone call.

It is noted that due to the American long weekend, the documents requested will be provided by Wednesday 10th July, 12pm.

Please see below a range of options for the communication strategy – i.e. publishing the Print media Advert with the black triangle:

- JNJ website statement;
- JNJ Social Media Statements;
- TGA will publish on our website;
- TGA on their Facebook and twitter;
- ACCC website (TGA notified);
- Primary Healthcare Network (DoH) (TGA notified);
- Combination of National and/or State newspapers; and
- Media Release by JNJ.

The Recalls team is experimenting with a new template for organising communication strategies for consumer level recalls.

Could you please populate this document with relevant information regarding your own consumer notification strategy and provide it ASAP.

If you need any help or wish to discuss this please feel free to give me a call.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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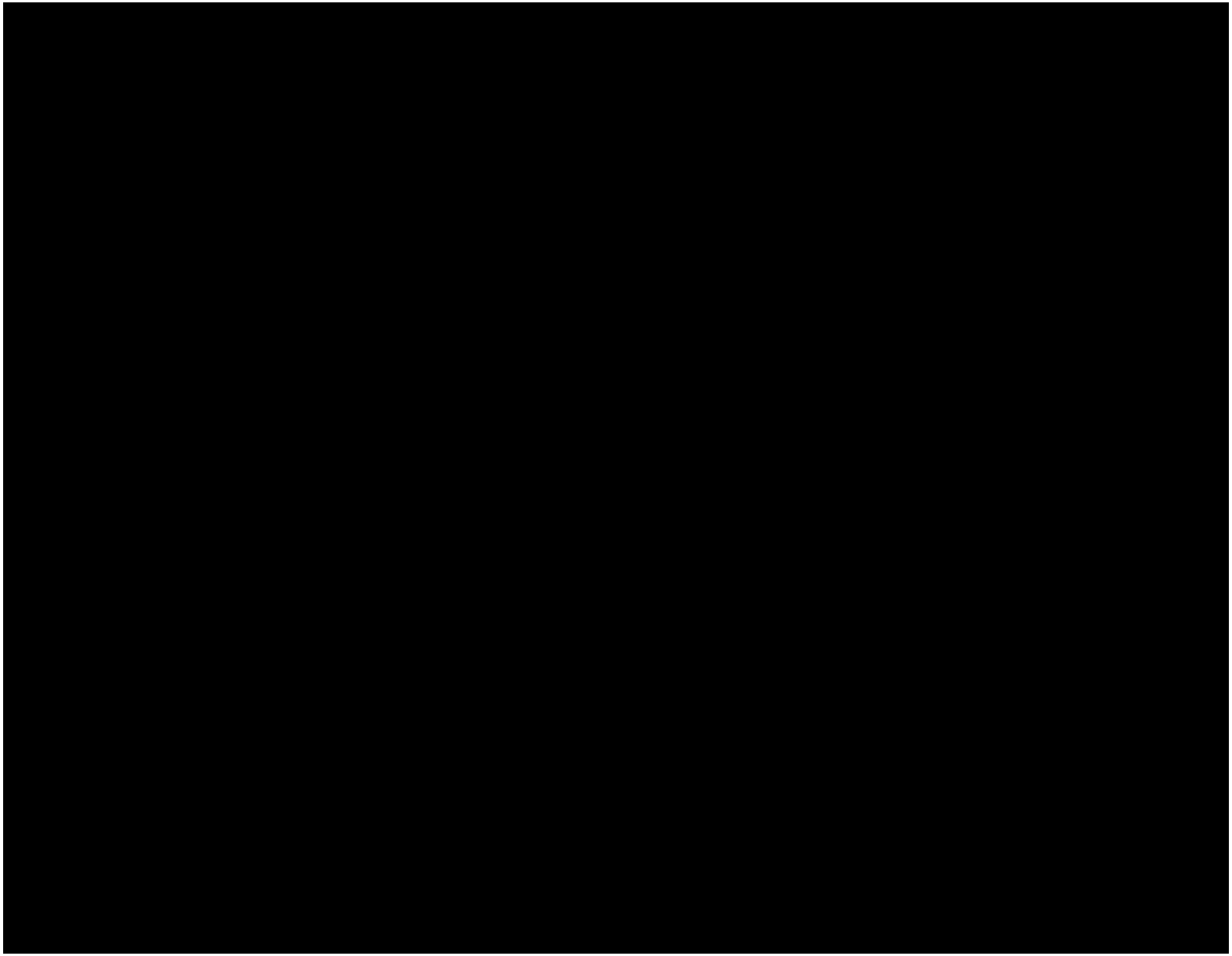
jnj_aware_dt	issue_cntry	tracking_no	prod_nm
20/10/2017	Australia	30001357122	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
13-Nov-17	Australia	30001363818	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
15-Jan-18	Australia	30001388143	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
28-Mar-18	Australia	30001412890	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
28-Mar-18	Australia	30001412891	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
19-Jun-18	Australia	80000008919	NEUTROGENA LIGHT THERAPY ACNE MASK AP 26202031B 0026202031APB
13-Aug-18	Australia	80000015316	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
18-Sep-18	Australia	80000019222	NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 3574661329499 0026202031APA 0026202031APA
1-Nov-18	Australia	80000024717	NEUTROGENA LIGHT THERAPY ACNE MASK AP 26202031B 0026202031APB
29-May-19	Australia	80000055349	NEUTROGENA LIGHT THERAPY ACNE MASK AP 26202031B 0026202031APB
29-May-19	Australia	80000055349	NEUTROGENA LIGHT THERAPY ACNE MASK AP 26202031B 0026202031APB

lot_no
NOT AVAILABLE
1407KS06
NOT AVAILABLE
1447K506
N/A
N/A
1457KS06
1447KS06
1577KS06
N/A
N/A

iss_rptr_desc
MADE MY MOTHER FEEL DIZZY FOR ABOUT 30 SECONDS
CONSUMER HAS RETURNED COMPLETED MEDICAL INFORMATION SURVEY
I used the light activator mask for the first time, I could clearly see a blue light even though my eyes were shut. After 10 minutes, I opened my eyes and everything w
CUSTOMER SAID HER EYES STING AND ARE WATERY FOR A LITTLE WHILE AFTER EACH TIME IS USES THE MASK
IS IT NORMAL THAT AFTER THE USE OF THE MASK THAT ALL I HAVE BEEN SEEING IS GREEN? LIKE IM STILL WAITING FOR MY EYES TO ADJST BACK BUT EVERYTHING IS
My skin was red underneath my eye after using this product a couple of times and my vision was a bit blurry. First time user.
used this product a couple of times however my eyes will not stop watering and they are a bit swollen
each time my daughter uses this mask her eyes a blurry for a little while afterwards, she has only used it around 6 times
Can you tell me if this product is safe on the eyes? My teenage daughter has been using this product for about a month and now we've been told she has to wear gla
I have been using the Light therapy for 3 nights now. On the third night I used it whilst wearing my contact lenses and then went to sleep. When I woke up in the mo
I have been using the Light therapy for 3 nights now. On the third night I used it whilst wearing my contact lenses and then went to sleep. When I woke up in the mo

prod_mfg	prod_cd	reg_class	alert_limit	alert_lmt_reached	cat_lvl2_desc
[redacted]	002620203	MEDICAL DEVICE II	5		Medical Adverse Event
Unknown	002620203	MEDICAL DEVICE II	5		Medical Adverse Event
Unknown	002620203	MEDICAL DEVICE II	5		Medical Adverse Event
[redacted]	002620203	MEDICAL DEVICE II	5		Medical Adverse Event
	002620203	MEDICAL DEVICE II	5		Medical Adverse Event
	002620203	MEDICAL DEVICE II	5	N/A	Medical Adverse Event
	002620203	MEDICAL DEVICE II	5	No	Medical Adverse Event
	002620203	MEDICAL DEVICE II	5	No	Medical Adverse Event
	002620203	MEDICAL DEVICE II	5	No	Medical Adverse Event
	002620203	MEDICAL DEVICE II	5	N/A	Medical Adverse Event
	002620203	MEDICAL DEVICE II	5	N/A	Medical Adverse Event

cat_lvl3_desc	seriousness
Neurological Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Adverse Event
Visual Disorder/Disturbance	Serious AE
Eye Disorder/Disturbance	Adverse Event
Eye Disorder/Disturbance	Adverse Event



Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask

and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator

AFFECTED DEVICES:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

On behalf of this organisation I acknowledge receipt of the Medical Device Recall notice date Wednesday 10th July 2019 relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	**Batch/Lot/Date**	**Quantity of stock received**	**Quantity of unused stock subject to recall (currently in quarantine)**
Neutrogena Visibly Clear Light Therapy Acne Mask and Activator			
Neutrogena Visibly Clear Light Therapy Acne Mask Activator			
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Name	[redacted]
Position	[redacted]
Organisation	Johnson & Johnson Pacific
Address	45 Jones Street, Ultimo NSW 2007
Email	[redacted] its.jnj.com
Subject of email	Neutrogena Visibly Clear Light Therapy Acne Mask and Activator
Telephone no.	1800 638 047 (press '2')

Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: [X] July 2019.

Dear [customer name],

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Customers are advised that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator are being withdrawn and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers in Australia should be advised to discontinue use and contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or neutrogenamaskAU@its.jnj.com to return the device and arrange for a refund.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com

Actions to be taken:

Our records show that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further distribution;
- Complete the **Recall Acknowledgement Form** (attached) immediately, whether you have affected medical devices or not and return the form to **CustomerService2@ITS.JNJ.COM** ;
- If the affected medical devices have been forwarded to a retail store, contact that retailer with the attached **Letter to Retailers** and the **Recall Acknowledgement Form**, which they need to fill in and return to you, whether they have affected medical devices or not;
- Before you raise a credit claim, please ensure you have collected all acknowledgement forms and affected devices from your retailers;
- Raise a credit claim in your system and email the claim and the consolidated Acknowledgement Forms to **CustomerService2@ITS.JNJ.COM;**

- Once the claim has been received, Johnson & Johnson Pacific Customer Service will contact you to provide your return number and pick up instructions.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products, which is why we have voluntarily initiated this process.

If you have any other questions, please don't hesitate to contact your business manager.

Yours sincerely

[redacted]
Johnson & Johnson Pacific

Johnson & Johnson Pacific

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2019-RN-00986-1

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

[ARTG ID: 287825. First available to customers in July 2017]

Date: X July 2019

Dear Retailer,

Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a consumer level in Australia. We are contacting you as the affected product has been supplied to your organisation.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Mask Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask + Activator	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment.

Johnson & Johnson Pacific

Reason for recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of generally mild, rare and transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

There is a theoretical risk of eye injury for a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity. We have not received any reports of eye injury in this small subset of individuals with the underlying eye conditions.

This recall is being conducted as a precautionary measure. Retailers are advised that the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator are being withdrawn and will no longer be supplied.

In alignment with the recommendation of the TGA, consumers in Australia should be advised to discontinue use and contact the Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348 or neutrogenamaskAU@its.jnj.com to return the device and arrange for a refund.

If consumers experience any adverse symptoms, they should contact their healthcare professional and report the incident to the Johnson & Johnson Pacific Consumer Care Centre at consumer@its.jnj.com

Actions to be taken:

We understand that you have received one or more of the devices subject to this recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Inspect your stock immediately and quarantine affected stock to prevent further distribution;
- Complete the **Recall Acknowledgement Form** (attached) immediately whether you have stock or not;
- Return the acknowledgement form with your existing inventory to the wholesaler you obtained it from and arrange for a credit;
- Please direct all consumer returns to the Johnson & Johnson Pacific Consumer Care Centre at neutrogenamaskAU@its.jnj.com to organise the return of all affected devices and arrange a refund.
- Place this letter in a prominent position for at least one month.

Ensure relevant staff members are informed of this recall.

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall immediately by providing a copy of this letter and the Recall Acknowledgment Form.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products which is why we have voluntarily initiated this action.

Yours sincerely

[redacted]
Johnson & Johnson Pacific

[Sponsor Name] Consumer-Level [Action]
[Product Name]

Consumer Level Communications Strategy

[Date]

SPONSOR KEY INFORMATION:

- The sponsor arranges and pays for consumer recall notices which are required for consumer level recalls unless they have complete and accurate distribution lists identifying the end-users.
- Prepare a communication strategy for your recall action, including draft consumer recall notices, which we will review and agree in consultation with you, or instruct in decisions relating to mandatory recalls.
- You should arrange for publication or broadcast of your notice in all forms of media agreed, within three to four business days after sending the customer letter as agreed with us, or as instructed in decisions relating to mandatory recalls.

Templates can be found at: https://www.tga.gov.au/form/urptg-templates

OVERVIEW & KEY MESSAGES

- [Description of Product(s)]
- [Description of Issue]
- [Description of Health Risks]
- [Description of Consumer Actions to be Taken]
- [Contact Information for Consumers]
- [Method of Product Recovery, Disposal or Correction]
- [Any Further Key Information]

Consumer Level Communications Strategy

[Date]

COMMUNICATIONS OBJECTIVES

The sponsor should tailor notices for specific groups of consumers. For example, it may be appropriate for the notices to be in other language(s) as well as English when the goods were sold to customers from specific non-English speaking backgrounds.

- [Statement of Objectives]
- [Estimated Outcome (Including Timeframe)]

COMMUNICATIONS ASSETS TO BE PRODUCED

Where the agreed communication strategy includes publication of your notice in print media daily newspapers, you should ensure the notice will be published:

- Once, in the daily print media newspapers (of each state and territory where the goods were possibly distributed); and
- Preferably in one of the first ten pages of the newspaper; and
- With a minimum size of double column width and 10 cm depth enclosed in a diagonally hatched border (refer to the example notice).

- [TGA Notification Letter]
- [Consumer Newspaper Advertisement]
- [Customer letter]
- [Sponsor/Manufacturer Website Post]
- [Social Media Posts]
- [Internal Communications]
- [Television or Radio]
- [Professional medical Colleges and Societies]
- [Community Forums and Focus Groups]

[Sponsor Name] Consumer-Level [Action]
[Product Name]

Consumer Level Communications Strategy

[Date]

- [Peak Consumer Groups (Consumers' Health Forum, Australian Consumers' Association)]
- [Patients Enrolled In Sponsor Developed Patient Support Programs]
- [Health Professionals and their Patients Enrolled in Sponsor Initiated Product Familiarisation Programs]
- [Industry Forums and Focus Groups]

KEY TIMINGS

[Date]
- [Action]
- [Action]

[Sponsor Name] Consumer-Level [Action]
[Product Name]

Consumer Level Communications Strategy

[Date]

COMMUNICATIONS STAKEHOLDER TIMEFRAME MATRIX:

STAKEHOLDER	What/Action	Media outlet/channel	Signature	DATE
EXTERNAL				
[Consumers]	[Media Advertisement]	[State and Territory Newspapers]	[Signature]	[Date Actionable]
INTERNAL				
[Internal Staff]	[Internal Quarantine Letter]	[Phone Call]	[Signature]	[Date Actionable]
GOV/INDUSTRY CONTACTS				
[ACCC]	[Letter Of Notification]	[Letter via Email]	[Signature]	[Date Actionable]

URGENT MEDICINE RECALL

<PRODUCT NAME> ELIXIR

120mg paracetamol per 5mL

100mL bottle

Batch number xxxxx, Expiry date: Oct 2017

AUST R xxxxx

<Company> Pty Ltd, Following consultation with the Therapeutic Goods Administration, is recalling batch xxxxx of <Product name> (which is an analgesic used to treat aches, pains and feverish conditions) because eucalyptus oil has been found in some bottles of this batch. No other batches of <Product name> Elixir are affected by this recall.

If you have a bottle of <Product name> Elixir from batch xxxxx, do not use it. Return it to the place of purchase for a refund or call our customer service line to arrange the return of affected product and refund.

CUSTOMER SERVICE 1800 xxx xxx

Ingestion of eucalyptus oil (other than in small amounts as in throat lozenges and inhalations etc.) may be harmful. As little as a few millilitres of eucalyptus oil may cause nausea, vomiting, dizziness, muscular weakness, delirium and convulsions. Anyone who is concerned in any way about the use of this product should consult their doctor.

<Company name> Pty Ltd sincerely regrets any inconvenience to their customers.

From: Recalls
To: [redacted][JJPAU]"
Cc: [redacted]@its.jnj.com; [redacted]@its.jnj.com; [redacted][CONAU]";
Subject: Request for Recall Action - Neutrogena Visibly Clear Light Therapy Acne Mask - RC-2019-RN-00986-1 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 5 July 2019 11:45:58 AM
Attachments: image002.png
BOXED Blank Recall Letter Template.docx

Dear [redacted]

Thank you and your team for the teleconference attendance.

After detailed further internal considerations between the TGA Medical Officers and the Director of the TGA Recalls section, it was again concluded that a Class II Consumer Level Recall is required to appropriately resolve this matter.

Some of the key points considered were:

- J&J states that the safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects;

- J&J has identified that in potentially susceptible populations 'Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss.'
    - o Given the activator will be no longer sold, the device is essentially being withdrawn. The TGA understands that the mask can be 'hacked' by various simple methods available online - in order to prolong the use of the device beyond the 30x10min sessions, and in a setting of discontinued supply this hacking will likely be incentivised for people at home, whom have a mask that is otherwise unusable. This would put their health at risk.
    - o Additionally, J&J States 'Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population'.
    - o J&J states "New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration";

- The current Instructions for Use (IFU) for this device do not describe any risks of eye injury or vision loss; and

- Importantly, the Field Safety Notice published on 19.JUN.2019 by MHRA includes the statement**:** "If consumers have questions or concerns, **or if they would like to return the product and the activator**, they are encouraged to contact us at crc@its.jnj.com."

    - o This indicates that J&J is in effect performing a Consumer Level Recall for this device in the UK, which is congruent with TGAs assessment of the matter, despite the documents generic title of "Field Safety Notice".

Please provide a suitable Updated Recall letter, Updated Customer List and Updated Acknowledgement Form as per the current URPTG by Midday Monday 8th July.

A boxed style template is attached for your convenience.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto[redacted]@ITS.JNJ.com]
Sent: Friday, 28 June 2019 3:11 PM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank-you for confirming the availability of the Medical Officer(s).

I would initially like to confirm that Tuesday at 10 am is suitable for teleconference for all J&J participants. Please advise if you need me to set up a teleconference or if you would prefer to use the TGA's conference call facilities.

From J&J the Participants in our conversation will be:

- [redacted] – (Local) [redacted]@its.jnj.com)
- [redacted] – (Local) [redacted]@ITS.JNJ.com)
- [redacted] – (Global) [redacted] – Consumer [redacted]@its.jnj.com)
- [redacted] – (Global) [redacted]@its.jnj.com)

We would like to take this opportunity to provide you with our comments for discussion and an update on the global recall status of discussions with other regulators for the NEUTROGENA® Light Therapy Acne Mask (NLTAM).

Global Recall Status Update

Countries where a **retail level recall** has been agreed to:

- Canada
- UK
- Ireland
- Portugal
- Austria
- Germany
- New Zealand

Countries where a decision/alignment is pending:

- Spain
- France
- USA

There are no other countries where a confirmed consumer level recall has been requested at this point in time.

TGA Comment

#1 - *"The sponsor reports 359 cases of visual/eye signs or symptoms of which they classified seven as serious and 85 cases of neurologic sign or symptoms, where 35 of the consumers attributed these to the light exposure. 3 of these were classed as serious.* **#2** - *"Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness."*

Response

#1 We would like to further clarify with the TGA Medical Officers that the 3 cases classified as serious in the Health Hazard Evaluation (HHE) were labelled as such due to their medical significance.

None of the reported serious cases are in scope of the potential retinal hazard associated with blue light as reported in the HHE. Overall for neurological disorder the reporting frequencies were very rare to rare.

The 3 cases classified as medically serious were:

- Optic neuritis (n=1),
- Seizure (n=1), and
- Idiopathic intracranial hypertension (n=1)

#2 We would like to further discuss the statement that *"Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness."*

The HHE states (page 2) that new research has raised questions about the **potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration**.

Testing on the NLTAM and discussions with experts revealed, and as stated in the HHE, that because of the position of the lower LEDs on the device, exposure to peripheral retina is expected and indirect illumination of the macula. As such it is not expected that the use of the mask would result in macular injury

The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. **The theoretical harms are based on extrapolations of what is known about potential effects** of intense light in some of these groups. This is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that might not be directly applicable to the exposure conditions of the NLTAM.

Moreover, there is no evidence in post-marketing surveillance of any permanent harm and the incidences of transient light effects are rare. It is almost certain that use will be self-limiting after 1-2 uses in users with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity, because of the prolonged and transient effects described in the HHE. Therefore, it is almost certain that no permanent damage would occur from devices that are in the market.

TGA Comment

#3 *The sponsor has identified that in potentially susceptible populations 'Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss.'*
Potentially susceptible populations include persons with these disorders:
• *Retinitis Pigmentosa*
• *Ocular Albinism*
• *Photosensitive Medication*
• *Other Hereditary Ocular Disorders.*

Response

#3 The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. **We would like to take this opportunity to explain and discuss the theoretical harms and how they are based on extrapolations of what is known about potential effects** of intense light in some of these groups.

As stated above, it is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that may not be directly applicable to the exposure conditions of the NLTAM.

Moreover, there is **no evidence** in post-marketing surveillance of any risk of permanent harm and the incidences of transient light effects are rare.

It is almost certain that use by susceptible populations will be self-limiting after 1-2 uses. This is because of the prolonged and transient effects described in the HHE, including intense discomfort to light.

TGA Comment

#4 *The sponsor also states that the safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.*

Importantly intended users of this device have mild-moderate acne vulgaris. Tetracycline antibiotics e.g. doxycycline and minocycline and the oral contraceptive pill are commonly used to treat moderate acne vulgaris. Oral isotretinoin is used for severe or cystic acne. The aforementioned medications used to treat acne vulgaris are all associated with an increased risk of ocular photosensitivity. There is a very real possibility that many of the users of this device may be taking one or more of the aforementioned photosensitising medications. Importantly, the precautions section of the IFU does not mention ocular photosensitivity or underlying ocular disorders. Therefore, users will be unable to tell from the instructions for use whether it is safe for them to use this device.

Response

#4 The IFU states "*Discontinue use if you experience any discomfort*". The IFU also states "*Do not use device if your skin is light sensitive or you are currently using medication that may cause sensitivity of skin to light.*"

Whilst it is well established that some prescription medicines such as the tetracyclines, oral contraceptive pill, or isotretinoin can increase an individual's dermatological susceptibility to light, there is currently no evidence that these medicines also increase ocular sensitivity to light.

The HHE outlines that there is a theoretical risk that some medicines could potentially enhance ocular photosensitivity with use of the NLTAM. It is unclear which medicines, if any, have this potential. It is important to note that not all medicines that may potentially increase skin sensitivity to light would be expected to potentially increase retinal sensitivity to light to the same degree or in a similar fashion.

In any event, patients that might be using these prescription medicines are made aware of the increased dermatological photosensitivity through pharmacist labelling and counselling at time of purchase.

TGA Comment

#5 ***Importantly, the instructions for use for this device do not describe any risks of eye injury or vision loss.***

Response

#5 The IFU does not specifically describe the theoretical risk of ocular injury or damage for the susceptible sub population. The IFU does however state "*…Although the use of light therapy, such as used with the Light Therapy Acne Mask has been shown to be safe, there may be unforeseeable risks that have not been identified at this time…*"

Reports of visual effects associated with use of the NLTAM are rare, generally mild and transient.

For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, ***there is a theoretical risk of eye injury***. However, the potential risk of permanent retinal injury in this population is mitigated by the assessment that it is almost certain that initial use of the mask will be self-limiting due to the aversive signs and symptoms. Therefore, it is **almost certain that no permanent damage** would occur from devices that are in the market

There are no reports in the company's global safety database associated with the NLTAM

that identify individuals with these underlying eye conditions or suggest that permanent ocular injury has occurred in this subset of users.

TGA Comment
#6 ***For all the aforementioned I advise the Hazard classification be changed to Class 1.***

And

The subject device should therefore, be fully recalled at the consumer level as the proposed recall action does not mitigate the risk for consumers who have already purchased this product."

Response
#6 We respectfully request a better understanding of the TGA's perspective in relation to the proposed classification of Class I (as defined in the current URPTG as being the most serious safety-related - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death)

We do not align with the proposed category Class I, especially given the fact that this product has been marketed (globally) since 2016 and there have been **no reported adverse events related to exposure to blue light**

We maintain our position that the most appropriate course of action is a Class III, retail level recall, in line with other respected regulators.

TGA Comment
#7 *Additionally the sponsor states 'Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population'. The sponsor also states "New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration".*

Response
#7 We would like to the discuss about the statement ""*New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration".*

Testing on the NLTAM and discussions with experts revealed, and as stated in the HHE, that because of the position of the lower LEDs on the device, exposure to peripheral retina is expected and indirect illumination of the macula. As such it is not expected that the use of the mask would result in macular injury

The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. **The theoretical harms are based on extrapolations of what is known about potential effects** of intense light in some of these groups. It is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that may not be directly applicable to the exposure conditions of the NLTAM. Moreover, there is no evidence in post-marketing surveillance of any risk of permanent harm and the incidences of transient light effects are rare.

It is almost certain that use will be self-limiting after 1-2 uses in users with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity. Susceptible populations would experience intense discomfort to light as well as prolonged but transient adaptation defects. Therefore, it is **almost certain that no permanent damage** would occur from devices that are in the market.

-

-

TGA Comment

-

#8 *Misuse by "wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2 retinal exposure guideline of ANSI Z80.36-20163." Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an enthusiastic juvenile is possible. This again highlights the need for a consumer level recall."*

Response

#8 There are adequate instructions to ensure the device is used only once per day.

- Page 2 of the IFU states "*use the Light Therapy Acne Mask, once a day, every day for best results"*.
- Page 8 of the IFU states **"***use the Light Therapy Mask once daily***".**

Additionally, page 13 of the IFU states, "*Keep the device out of reach of children*". This warning statement should be considered more than adequate to address the fact that this product is not suitable for children.

It is worth noting that orally administered solid dose medicines which are likely to have a greater risk profile when misused by comparison to the NLTAM) contain the warning of "*keep out of reach of children*". There are no mandated warning statements required on medicines to the effect that supervision is required when administering to children. It stands to reason that a product with a lower risk profile should not require additional warning statements.

Although the IFU does not explicitly call out *for use age 12 years and older*, it is our website (https://www.neutrogena.com.au/visibly-clear-acne-light-therapy-faqs) that states the intended user. Additionally, this product is sold in pharmacies, consequently there is opportunity for consumers to seek counselling prior to purchase.

Kind Regards

[redacted]

[redacted]

Pacific & North Asia

Johnson & Johnson Pacific
Locked Bag 5, BROADWAY NSW 2007 AUSTRALIA
45 Jones Street ULTIMO NSW 2007 AUSTRALIA

Tel: [redacted] | Mobile: [redacted]
Email: [redacted]@its.jnj.com

From: Recalls <Recalls@health.gov.au>
Sent: Thursday, 27 June 2019 12:02 PM
To: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>; [redacted] [redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

I have spoken with the Medical Officers(MOs).

Tuesday 2nd July – 10:00am is available for a teleconference.

Could you please provide the MOs a list of questions or concerns for discussion during the teleconference.
Given the statement from the MOs in previous emails – What major concerns/issues do you have with the assessment of a CLASS I Consumer Level Recall.
Please provide this by **12pm Friday 28th June** to allow the MOs time to prepare a response.

If this date and time is acceptable for you, I will send out a Calendar invite email shortly with instructions on how to join the teleconference on the day.

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [JJPAU] [mailto [redacted]@ITS.JNJ.com]
Sent: Thursday, 27 June 2019 10:58 AM
To: Recalls
Cc: [redacted][JJPAU]; [redacted][CONAU]; [redacted]
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Just coming back to you on the email below – we would definitely still like to have a teleconference. As our global safety/medical team is based in New Jersey in the USA, if we could arrange for a call on Tuesday morning, if the TGA's medical officers are available, we would be most grateful.

Kind regards

[redacted]

From: [redacted]<[redacted]@health.gov.au> **On Behalf Of** Recalls
Sent: Wednesday, 26 June 2019 3:29 PM
To: [redacted][JJPAU] <[redacted]@ITS.JNJ.com>
Cc: [redacted][JJPAU] [redacted]@ITS.JNJ.com>; [redacted][CONAU] <[redacted]@its.jnj.com>; [redacted]<[redacted]@health.gov.au>
Subject: [EXTERNAL] RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

So I've had a quick chat to the clinical area and their availability this week is quite limited so we will likely need to push back any teleconference into next week if required.
Given that you indicated that Ireland had asked similar questions and there is a teleconference planned with them this evening is it possible to send through a summary of outcomes of this?

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100

Woden ACT 2606
www.tga.gov.au

Additionally, the clinical area

From: [redacted] [mailto [redacted]@health.gov.au] **On Behalf Of** Recalls
Sent: Wednesday, 26 June 2019 2:27 PM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Thank you for your time on the phone just now and thank you for raising that the original email did not contain the attachments as specified (apologies!).
As discussed, I'll touch base with my colleagues in the clinical area to schedule a teleconference to discuss the issues outlined below. As I will be out of the office from tomorrow I have cc'd in my colleague [redacted] who will likely take this over from the Recalls Section.
As soon as I can confirm the availability of the clinical area I will send through the details.

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From [redacted] [mailto:[redacted]@health.gov.au] **On Behalf Of** Recalls
Sent: Wednesday, 26 June 2019 9:10 AM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

This action has been reviewed by our clinical area who have made the following comments regarding this action:

"The sponsor reports 359 cases of visual/eye signs or symptoms of which they classified seven as serious and 85 cases of neurologic sign or symptoms, where 35 of the consumers attributed these to the light exposure. 3 of these were classed as serious. Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness.

The sponsor has identified that in potentially susceptible populations 'Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss.'
Potentially susceptible populations include persons with these disorders:
- *Retinitis Pigmentosa*
- *Ocular Albinism*
- *Photosensitive Medication*
- *Other Hereditary Ocular Disorders.*

The sponsor also states that the safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.
Importantly intended users of this device have mild-moderate acne vulgaris. Tetracycline antibiotics e.g. doxycycline and minocycline and the oral contraceptive pill are commonly used to treat moderate acne vulgaris. Oral isotretinoin is used for severe or cystic acne. The aforementioned medications used to treat acne vulgaris are all associated with an increased risk of ocular photosensitivity. There is a very real possibility that many of the users of this device may be taking one or more of the aforementioned photosensitising medications. Importantly, the precautions section of the IFU does not mention ocular photosensitivity or underlying ocular disorders. Therefore, users will be unable to tell from the instructions for use whether it is safe for them to use this device.

Importantly, the instructions for use for this device do not describe any risks of eye injury or vision loss.

For all the aforementioned I advise the Hazard classification be changed to Class 1.

Additionally the sponsor states 'Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can

potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population'. The sponsor also states "New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration". ***The subject device should therefore, be fully recalled at the consumer level as the proposed recall action does not mitigate the risk for consumers who have already purchased this product."***

And;

"Misuse by "wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2 retinal exposure guideline of ANSI Z80.36-20163." Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an enthusiastic juvenile is possible. This again highlights the need for a consumer level recall."

Some amendments have been made to the draft wholesale and retail letters (see attached). Please review and advise.

Given the above, please provide a draft consumer level advertisement and communication strategy (per pages 60-63 URPTG).

Otherwise, happy to discuss further.

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [CONAU] [mailto [redacted]@its.jnj.com]

Sent: Monday, 24 June 2019 2:30 PM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Thankyou for your email. Please see our responses below. As [redacted] from tomorrow [redacted] (cc) will now take over this from me.

Kind regards

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

From: [redacted] <[redacted]@health.gov.au> **On Behalf Of** Recalls
Sent: Monday, 24 June 2019 12:10 PM
To: [redacted] [CONAU] [redacted]@its.jnj.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>; [redacted] [JJPAU] [redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Thank you for sending this information through. To further assess this action can you please advise on the following:

1. Have any adverse events been reported in Australia? There have been no confirmed Adverse Events reported in Australia
2. Are there alternative activators that can be used with this model? No
3. How many units are in distribution in the Aus market? There are [redacted] units of the mask and [redacted] units of the activator in the wholesaler channel. From a retailer perspective unfortunately we don't have visibility of the number of units

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [CONAU] [mailto:[redacted]@its.jnj.com]
Sent: Friday, 21 June 2019 3:55 PM
Subject: Attention [redacted]- Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=No Protective Marking]
Importance: High

Dear [redacted]

Thank you for the phone conversation yesterday afternoon regarding our NEUTROGENA® Visibly® Clear Light Therapy Acne Mask and activator that Johnson & Johnson Pacific (JJP) would like to conduct a voluntary Class III recall from wholesalers and retailers.

Background information

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask on the eye. Out of an abundance of caution, we have made the voluntary decision to recall the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator at the wholesale and retail levels. We have initiated a global stop-ship on this product and the activator.

Description of device and its intended application

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of Red and Blue light via light-emitting diodes (LEDs), and weighs less than 400g.

NEUTROGENA® Visibly Clear Light Therapy Acne Mask and NEUTROGENA® Visibly Clear Light Therapy Acne Mask Activator is offered separately to increase the number of doses available from the Neutrogena® Visibly Clear® Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries**.**

Description and justification of the action

Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask are rare, generally mild and transient.

- For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury (further details are described in the Health Hazard Evaluation attached).
- It is predicted that users and misusers in this population would almost certainly develop intense light sensitivity and aversive symptoms (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in colour vision, abnormal visual acuity) with any use of the Mask, making further use self-limiting.
- The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is safe for use by the general population when used as directed.

Corrective action

Corrective action is not applicable as this model of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator will be discontinued globally for commercial reasons.

The following documentation is attached for your reference:

- ARTG entry
- HHE
- DRAFT customer (wholesaler), retailer letters and acknowledgment form
- Customer list – as per our phone conversation we have included the full list of wholesalers. Retailer information is difficult to obtain as it is owned by the wholesalers

We look forward to hearing from you on this matter. Please note I will be on leave from Tuesday 25th June and my manager, [redacted] will be the key contact. Please feel free to reach out to myself or my manager [redacted] [redacted]@ITS.JNJ.com) with any questions.

Kind regards,

[redacted]
[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

[redacted]
[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

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URGENT MEDICAL DEVICE RECALL or PRODUCT DEFECT CORRECTION

Product Name

ARTG:
Sponsor Ref: (if applicable)
TGA Ref:
Date: XX Month 2018

Dear [recipient],

[Company] is undertaking a [action type] of the above product. We are contacting you as our records indicate the potentially affected product [has been/ may have been] supplied to your organisation.

ISSUE	• Issue identified with product
HAZARD	• Hazards that may arise from use of potentially affected goods • •
CORRECTIVE ACTION BEING TAKEN	• Action undertaken by sponsor/manufacturer to rectify issue • •
INSTRUCTIONS FOR USERS	• Actions for customers both interim and long term if applicable • Include instructions for customer response form •
CONTACT INFORMATION	For questions regarding this letter, please contact: **Australian Contact Person**

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

We apologise for any inconvenience caused to your organisation.

Kind Regards,

From: Recalls
To: [redacted]
Subject: FW: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 28 June 2019 3:28:27 PM
Attachments: image002.png

Below is the response from J&J Regarding discussion topics for the conference call.

I will send out an email shortly, with the call in details for **Tuesday 02/07/2019 at 10:00 am.**

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto: [redacted]@ITS.JNJ.com]
Sent: Friday, 28 June 2019 3:11 PM
To: Recalls
Cc: [redacted] [JJPAU]; [redacted] [CONAU]
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

Thank-you for confirming the availability of the Medical Officer(s).

I would initially like to confirm that Tuesday at 10 am is suitable for teleconference for all J&J participants. Please advise if you need me to set up a teleconference or if you would prefer to use the TGA's conference call facilities.

From J&J the Participants in our conversation will be:

- [redacted] – (Local) [redacted]@its.jnj.com)
- [redacted] – (Local) [redacted]@ITS.JNJ.com)
- [redacted] – (Global) [redacted]
  [redacted]@its.jnj.com)

- [redacted] – (Global) [redacted]@its.jnj.com)

We would like to take this opportunity to provide you with our comments for discussion and an update on the global recall status of discussions with other regulators for the NEUTROGENA® Light Therapy Acne Mask (NLTAM).

Global Recall Status Update

Countries where a **retail level recall** has been agreed to:

- Canada
- UK
- Ireland
- Portugal
- Austria
- Germany
- New Zealand

Countries where a decision/alignment is pending:

- Spain
- France
- USA

There are no other countries where a confirmed consumer level recall has been requested at this point in time.

TGA Comment

#1 - *"The sponsor reports 359 cases of visual/eye signs or symptoms of which they classified seven as serious and 85 cases of neurologic sign or symptoms, where 35 of the consumers attributed these to the light exposure. 3 of these were classed as serious.* **#2** - *"Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness."*

Response

#1 We would like to further clarify with the TGA Medical Officers that the 3 cases classified as serious in the Health Hazard Evaluation (HHE) were labelled as such due to their medical significance.

None of the reported serious cases are in scope of the potential retinal hazard associated with blue light as reported in the HHE. Overall for neurological disorder the reporting frequencies were very rare to rare.

The 3 cases classified as medically serious were:

- Optic neuritis (n=1),
- Seizure (n=1), and
- Idiopathic intracranial hypertension (n=1)

#2 We would like to further discuss the statement that *"Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness."*

The HHE states (page 2) that new research has raised questions about the **potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration**.

Testing on the NLTAM and discussions with experts revealed, and as stated in the HHE, that because of the position of the lower LEDs on the device, exposure to peripheral retina is expected and indirect illumination of the macula. As such it is not expected that the use of the mask would result in macular injury

The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. **The theoretical harms are based on extrapolations of what is known about potential effects** of intense light in some of these groups. This is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that might not be directly applicable to the exposure conditions of the NLTAM.

Moreover, there is no evidence in post-marketing surveillance of any permanent harm and the incidences of transient light effects are rare. It is almost certain that use will be self-limiting after 1-2 uses in users with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity, because of the prolonged and transient effects described in the HHE. Therefore, it is almost certain that no permanent damage would occur from devices that are in the market.

TGA Comment

#3 *The sponsor has identified that in potentially susceptible populations 'Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss.'*
Potentially susceptible populations include persons with these disorders:
• *Retinitis Pigmentosa*
• *Ocular Albinism*
• *Photosensitive Medication*
• *Other Hereditary Ocular Disorders.*

Response

#3 The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. **We would like to take this opportunity to explain and discuss the theoretical harms and how they are based on extrapolations of what is known about potential effects** of intense light in some of these groups.

As stated above, it is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that may not be directly applicable to the exposure conditions of the NLTAM.

Moreover, there is **no evidence** in post-marketing surveillance of any risk of permanent harm and the incidences of transient light effects are rare.

It is almost certain that use by susceptible populations will be self-limiting after 1-2 uses. This is because of the prolonged and transient effects described in the HHE, including intense discomfort to light.

TGA Comment

#4 *The sponsor also states that the safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.*

Importantly intended users of this device have mild-moderate acne vulgaris. Tetracycline antibiotics e.g. doxycycline and minocycline and the oral contraceptive pill are commonly used to treat moderate acne vulgaris. Oral isotretinoin is used for severe or cystic acne. The aforementioned medications used to treat acne vulgaris are all associated with an increased risk of ocular photosensitivity. There is a very real possibility that many of the users of this device may be taking one or more of the aforementioned photosensitising medications. Importantly, the precautions section of the IFU does not mention ocular photosensitivity or underlying ocular disorders. Therefore, users will be unable to tell from the instructions for use whether it is safe for them to use this device.

Response

#4 The IFU states "*Discontinue use if you experience any discomfort*". The IFU also states "*Do not use device if your skin is light sensitive or you are currently using medication that may cause sensitivity of skin to light.*"

Whilst it is well established that some prescription medicines such as the tetracyclines, oral contraceptive pill, or isotretinoin can increase an individual's dermatological susceptibility to light, there is currently no evidence that these medicines also increase ocular sensitivity to light.

The HHE outlines that there is a theoretical risk that some medicines could potentially enhance ocular photosensitivity with use of the NLTAM. It is unclear which medicines, if any, have this potential. It is important to note that not all medicines that may potentially increase skin sensitivity to light would be expected to potentially increase retinal sensitivity to light to the same degree or in a similar fashion.

In any event, patients that might be using these prescription medicines are made aware of the increased dermatological photosensitivity through pharmacist labelling and counselling at time of purchase.

TGA Comment

#5 ***Importantly, the instructions for use for this device do not describe any risks of eye injury or vision loss.***

Response

#5 The IFU does not specifically describe the theoretical risk of ocular injury or damage for the susceptible sub population. The IFU does however state "…*Although the use of light therapy, such as used with the Light Therapy Acne Mask has been shown to be safe, there may be unforeseeable risks that have not been identified at this time…*"

Reports of visual effects associated with use of the NLTAM are rare, generally mild and transient.

For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, ***there is a***

theoretical risk of eye injury. However, the potential risk of permanent retinal injury in this population is mitigated by the assessment that it is almost certain that initial use of the mask will be self-limiting due to the aversive signs and symptoms. Therefore, it is **almost certain that no permanent damage** would occur from devices that are in the market

There are no reports in the company's global safety database associated with the NLTAM that identify individuals with these underlying eye conditions or suggest that permanent ocular injury has occurred in this subset of users.

TGA Comment
#6 ***For all the aforementioned I advise the Hazard classification be changed to Class 1.***

And

-
The subject device should therefore, be fully recalled at the consumer level as the proposed recall action does not mitigate the risk for consumers who have already purchased this product."

Response
#6 We respectfully request a better understanding of the TGA's perspective in relation to the proposed classification of Class I (as defined in the current URPTG as being the most serious safety-related - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death)

We do not align with the proposed category Class I, especially given the fact that this product has been marketed (globally) since 2016 and there have been **no reported adverse events related to exposure to blue light**

We maintain our position that the most appropriate course of action is a Class III, retail level recall, in line with other respected regulators.

TGA Comment
#7 *Additionally the sponsor states 'Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population'. The sponsor also states "New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration".*

Response
#7 We would like to the discuss about the statement ""*New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration".*

Testing on the NLTAM and discussions with experts revealed, and as stated in the HHE, that because of the position of the lower LEDs on the device, exposure to peripheral retina is expected and indirect illumination of the macula. As such it is not expected that the use of the mask would result in macular injury

The theoretical harms defined for potentially susceptible populations cover a heterogenous

group with varying clinical severity and risks. **The theoretical harms are based on extrapolations of what is known about potential effects** of intense light in some of these groups. It is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that may not be directly applicable to the exposure conditions of the NLTAM. Moreover, there is no evidence in post-marketing surveillance of any risk of permanent harm and the incidences of transient light effects are rare.

It is almost certain that use will be self-limiting after 1-2 uses in users with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity. Susceptible populations would experience intense discomfort to light as well as prolonged but transient adaptation defects. Therefore, it is **almost certain that no permanent damage** would occur from devices that are in the market.

-

-

TGA Comment

-

#8 *Misuse by "wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2 retinal exposure guideline of ANSI Z80.36-20163." Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an enthusiastic juvenile is possible. This again highlights the need for a consumer level recall."*

Response

#8 There are adequate instructions to ensure the device is used only once per day.

- Page 2 of the IFU states "*use the Light Therapy Acne Mask, once a day, every day for best results"*.
- Page 8 of the IFU states **"***use the Light Therapy Mask once daily***".**

Additionally, page 13 of the IFU states, "*Keep the device out of reach of children*". This warning statement should be considered more than adequate to address the fact that this product is not suitable for children.

It is worth noting that orally administered solid dose medicines which are likely to have a greater risk profile when misused by comparison to the NLTAM) contain the warning of "*keep out of reach of children*". There are no mandated warning statements required on medicines to the effect that supervision is required when administering to children. It stands to reason that a product with a lower risk profile should not require additional warning statements.

Although the IFU does not explicitly call out *for use age 12 years and older*, it is our website (https://www.neutrogena.com.au/visibly-clear-acne-light-therapy-faqs) that states the intended user. Additionally, this product is sold in pharmacies, consequently there is opportunity for consumers to seek counselling prior to purchase.

Kind Regards

[redacted]

[redacted]

Pacific & North Asia

Johnson & Johnson Pacific
Locked Bag 5, BROADWAY NSW 2007 AUSTRALIA
45 Jones Street ULTIMO NSW 2007 AUSTRALIA
Tel: [redacted] | Mobile: [redacted]
Email: [redacted]@its.jnj.com

From: Recalls <Recalls@health.gov.au>
Sent: Thursday, 27 June 2019 12:02 PM
To: [redacted][JJPAU] <[redacted]@ITS.JNJ.com>
Cc [redacted][JJPAU] [redacted]@ITS.JNJ.com>;[redacted][CONAU] [redacted]@its.jnj.com>
Subject: [EXTERNAL] RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL, ACCESS=Commercial]

Dear [redacted]

I have spoken with the Medical Officers(MOs).

Tuesday 2nd July – 10:00am is available for a teleconference.

Could you please provide the MOs a list of questions or concerns for discussion during the teleconference.
Given the statement from the MOs in previous emails – What major concerns/issues do you have with the assessment of a CLASS I Consumer Level Recall.
Please provide this by **12pm Friday 28th June** to allow the MOs time to prepare a response.

If this date and time is acceptable for you, I will send out a Calendar invite email shortly with instructions on how to join the teleconference on the day.

Kind Regards,

[redacted]

Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health

PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [JJPAU] [mailto:[redacted]@ITS.JNJ.com]
Sent: Thursday, 27 June 2019 10:58 AM
To: Recalls
Cc: [redacted][JJPAU]; [redacted] [CONAU]; [redacted]
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted] & [redacted]

Just coming back to you on the email below – we would definitely still like to have a teleconference. As our global safety/medical team is based in New Jersey in the USA, if we could arrange for a call on Tuesday morning, if the TGA's medical officers are available, we would be most grateful.

Kind regards

[redacted]

From: [redacted]@health.gov.au> **On Behalf Of** Recalls
Sent: Wednesday, 26 June 2019 3:29 PM
To [redacted][JJPAU] [redacted]@ITS.JNJ.com>
Cc: [redacted][JJPAU] <[redacted]@ITS.JNJ.com>; [redacted][CONAU] [redacted]@its.jnj.com>; [redacted]@health.gov.au>
Subject: [EXTERNAL] RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

So I've had a quick chat to the clinical area and their availability this week is quite limited so we will likely need to push back any teleconference into next week if required.
Given that you indicated that Ireland had asked similar questions and there is a teleconference planned with them this evening is it possible to send through a summary of outcomes of this?

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division

Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

Additionally, the clinical area

From: [redacted] [mailto [redacted]@health.gov.au] **On Behalf Of** Recalls
Sent: Wednesday, 26 June 2019 2:27 PM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Thank you for your time on the phone just now and thank you for raising that the original email did not contain the attachments as specified (apologies!).
As discussed, I'll touch base with my colleagues in the clinical area to schedule a teleconference to discuss the issues outlined below. As I will be out of the office from tomorrow I have cc'd in my colleague [redacted] who will likely take this over from the Recalls Section.
As soon as I can confirm the availability of the clinical area I will send through the details.

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [mailto:[redacted]@health.gov.au] **On Behalf Of** Recalls
Sent: Wednesday, 26 June 2019 9:10 AM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

This action has been reviewed by our clinical area who have made the following comments regarding this action:

"The sponsor reports 359 cases of visual/eye signs or symptoms of which they classified seven as serious and 85 cases of neurologic sign or symptoms, where 35 of the consumers attributed these to the light exposure. 3 of these were classed as serious. Exposure to blue UV light may cause macular degeneration which can lead to permanent vision loss and blindness.

The sponsor has identified that in potentially susceptible populations 'Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss.'
Potentially susceptible populations include persons with these disorders:
- *Retinitis Pigmentosa*
- *Ocular Albinism*
- *Photosensitive Medication*
- *Other Hereditary Ocular Disorders.*

The sponsor also states that the safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.
Importantly intended users of this device have mild-moderate acne vulgaris. Tetracycline antibiotics e.g. doxycycline and minocycline and the oral contraceptive pill are commonly used to treat moderate acne vulgaris. Oral isotretinoin is used for severe or cystic acne. The aforementioned medications used to treat acne vulgaris are all associated with an increased risk of ocular photosensitivity. There is a very real possibility that many of the users of this device may be taking one or more of the aforementioned photosensitising medications. Importantly, the precautions section of the IFU does not mention ocular photosensitivity or underlying ocular disorders. Therefore, users will be unable to tell from the instructions for use whether it is safe for them to use this device.

Importantly, the instructions for use for this device do not describe any risks of eye injury or vision loss.

For all the aforementioned I advise the Hazard classification be changed to Class 1.

Additionally the sponsor states 'Following a recent review by Johnson & Johnson Pacific Pty Ltd, it was determined that exposure to blue light from the Neutrogena Light Therapy Acne Mask can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population'. The sponsor also states "New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration". ***The subject device should therefore, be fully recalled at the consumer level as the proposed recall action does not mitigate the risk for consumers who have already purchased this product."***

And;

"Misuse by "wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2 retinal exposure guideline of ANSI Z80.36-20163." Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an enthusiastic juvenile is possible. This again highlights the need for a consumer level recall."

Some amendments have been made to the draft wholesale and retail letters (see attached). Please review and advise.

Given the above, please provide a draft consumer level advertisement and communication strategy (per pages 60-63 URPTG).

Otherwise, happy to discuss further.

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [CONAU] [mailto [redacted]@its.jnj.com]
Sent: Monday, 24 June 2019 2:30 PM
Subject: RE: RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Thankyou for your email. Please see our responses below. As I will be on annual leave from tomorrow [redacted] (cc) will now take over this from me.

Kind regards

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

From: [redacted]@health.gov.au> **On Behalf Of** Recalls
Sent: Monday, 24 June 2019 12:10 PM
To: [redacted] [CONAU] <[redacted]@its.jnj.com>
Cc: [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>; [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] RC-2019-RN-00986-1 Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Hi [redacted]

Thank you for sending this information through. To further assess this action can you please advise on the following:

1. Have any adverse events been reported in Australia? There have been no confirmed Adverse Events reported in Australia
2. Are there alternative activators that can be used with this model? No
3. How many units are in distribution in the Aus market? There are [redacted] units of the mask and [redacted] units of the activator in the wholesaler channel. From a retailer perspective unfortunately we don't have visibility of the number of units

Kind regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [CONAU] [mailto:[redacted]@its.jnj.com]
Sent: Friday, 21 June 2019 3:55 PM
Subject: Attention Sarah - Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=No Protective Marking]
Importance: High

Dear [redacted]

Thank you for the phone conversation yesterday afternoon regarding our NEUTROGENA® Visibly® Clear Light Therapy Acne Mask and activator that Johnson & Johnson Pacific (JJP) would like to conduct a voluntary Class III recall from wholesalers and retailers.

Background information

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask on the eye. Out of an abundance of caution, we have made the voluntary decision to recall the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator at the wholesale and retail levels. We have initiated a global stop-ship on this product and the activator.

Description of device and its intended application

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of Red and Blue light via light-emitting diodes (LEDs), and weighs less than 400g.

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator is offered separately to increase the number of doses available from the Neutrogena® Visibly Clear® Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries**.**

Description and justification of the action

Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask are rare, generally mild and transient.

- For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury (further details are described in the Health Hazard Evaluation attached).
- It is predicted that users and misusers in this population would almost certainly develop intense light sensitivity and aversive symptoms (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in colour vision, abnormal visual acuity) with any use of the Mask, making further use self-limiting.
- The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is safe for use by the general population when used as directed.

Corrective action

Corrective action is not applicable as this model of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator will be discontinued globally for commercial reasons.

The following documentation is attached for your reference:

- ARTG entry
- HHE
- DRAFT customer (wholesaler), retailer letters and acknowledgment form
- Customer list – as per our phone conversation we have included the full list of wholesalers. Retailer information is difficult to obtain as it is owned by the wholesalers

We look forward to hearing from you on this matter. Please note I will be on leave from Tuesday 25th June and my manager, [redacted] will be the key contact. Please feel free to reach out to myself or my manager [redacted] [redacted]@ITS.JNJ.com) with any questions.

Kind regards,

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: Recalls
To: [redacted]
Subject: [Internal Comms] RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 27 June 2019 11:40:31 AM
Attachments: image002.png
image003.png

No problems [redacted]

Would it be possible for one of your team members to do the same from a TGA perspective and I will forward this to the sponsor.

I will ask [redacted] to prepare questions for review ASAP.

- [redacted]

From: [redacted]
Sent: Thursday, 27 June 2019 11:38 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial] [SEC=OFFICIAL]

I am available however I would like them to send us their questions ahead of the meeting so we are able to properly attend to their concerns.

Regards
[redacted]

Sent with BlackBerry Work
(www.blackberry.com)

From: [redacted] <[redacted]@health.gov.au>
Date: Thursday, 27 Jun 2019, 11:35 am
To: [redacted]@health.gov.au>, [redacted]@health.gov.au>, [redacted]@health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hello All,

I will be taking over this issue from a recalls perspective as [redacted] is away until next Thursday.

The most recent email from [redacted] of J&J is below.

Would Tuesday morning (~10am) be acceptable for a teleconference?

In regards to the Ireland recall decision – Over the phone, [redacted] has informed me they have agreed on a retail level recall.
I have asked for an email confirmation – still pending.

Hi [redacted] & [redacted]

Just coming back to you on the email below – we would definitely still like to have a teleconference. As our global safety/medical team is based in New Jersey in the USA, if we could arrange for a call on Tuesday morning, if the TGA's medical officers are available, we would be most grateful.

Kind regards

[redacted]

Kind Regards,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted]
Sen
To: [redacted]
Cc: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial] [SEC=OFFICIAL]

Thanks [redacted] much appreciated.

Cheers
[redacted]

Sent with BlackBerry Work
(www.blackberry.com)

From: [redacted]@health.gov.au>
Date: Wednesday, 26 Jun 2019, 3:24 pm
To: [redacted]@health.gov.au>, [redacted]@health.gov.au>, [redacted]@health.gov.au>
Cc: [redacted]_health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

No worries – will touch base with J&J and see if it's still required after the Irish teleconference.
Thanks,
[redacted]

From: [redacted]
Sent: Wednesday, 26 June 2019 3:08 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial] [SEC=OFFICIAL]
Hi and agree [redacted] being out of office all today I have work due by lunchtime tomorrow and then I'm out in arvo.
If telecon is needed have next week pls.
Would be good to know what their concerns are prior to that.
Thx
[redacted]

Sent with BlackBerry Work
(www.blackberry.com)

From: [redacted]@health.gov.au>
Date: Wednesday, 26 Jun 2019, 2:51 pm
To: [redacted]@health.gov.au>, [redacted]@health.gov.au>, [redacted]@health.gov.au>
Cc: [redacted]@health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial] [SEC=OFFICIAL]
Hi [redacted] and this week [redacted] but I'm not sure of [redacted] availability this week.
Perhaps they can have their teleconference with Ireland and hold off on a meeting with TGA if their clinical questions are answered by that conference with Ireland (given we have apparently asked the same questions).
Otherwise timing will need to be renegotiated if [redacted] is not available.
Regards
[redacted]

Sent with BlackBerry Work

(www.blackberry.com)

From: [redacted]@health.gov.au>
Date: Wednesday, 26 Jun 2019, 2:36 pm
To: [redacted]@health.gov.au>, [redacted]
<[redacted]@health.gov.au>, [redacted]@health.gov.au>
Cc: [redacted]@health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Thanks [redacted]
I have provided the clinical comments to J&J who have now requested a teleconference to discuss these with their clinical area overseas (US). Given the time difference J&J have requested **10am Friday**. If you could please confirm your availability for this that would be lovely [redacted] if you could also please advise).
Andrew from J&J indicated that they have a teleconference with Ireland this evening as they have asked similar questions to us. He did however indicate that MedSafe and MHRA have agreed to the retail level action (FDA and other EU regulators still pending).
At this stage I'll be handing this one over to [redacted] cc'd) as I will be out of the office for the next week from tomorrow. Noting you are out today, if you could please advise your availability to him upon your return [redacted] will send through the teleconference details from there.
Thanks,
[redacted]

From: [redacted] [mailto [redacted]@health.gov.au]
Sent: Wednesday, 26 June 2019 6:46 AM
Subject: FW: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial] [SEC=OFFICIAL]

Good morning [redacted]
I have completed the WP2 for this recall (it is filed in trim : D19-5680162) and also made some changes to the retail and wholesale letter. [redacted] and [redacted] have reviewed too and are happy with the proposed changes and action (see below email thread). I am in Canberra in a meeting all day today so won't be accessing my emails but [redacted] is in the office if you have any urgent queries. Otherwise I will be back in the office tomorrow.
Kind regards,
[redacted]

Sent with BlackBerry Work
(www.blackberry.com)

From: [redacted]@health.gov.au>
Date: Tuesday, 25 Jun 2019, 8:19 pm
To: [redacted]@health.gov.au>
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Great work [redacted] can you send them to [redacted] please.
Regards
[redacted]

From: [redacted]

Sent: Tuesday, 25 June 2019 4:49 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Forgot to say in the last email after you have had a chance to review the retail and wholesale letter can you let me know if you are happy for me to forward them and the WP2 to [redacted]

Thanks,

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 4:23 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi thanks [redacted]

Yes I've made tracked edits to the retail and wholesale letters but didn't see a specific customer letter?

Retail Letter: D19-5669941

Wholesale Letter: D19-5669942

I don't think [redacted] mentioned a customer letter in her original email (below).

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 3:58 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Looks good. Did you have to edit the customer letter also?

[redacted]

From [redacted]
Sent: Tuesday, 25 June 2019 1:02 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

WP2 updated D19-5680162 and Jo's additional advice added.

Thanks,

[redacted]

From [redacted]
Sent: Tuesday, 25 June 2019 12:39 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Awesome thanks

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 12:37 PM
To: [redacted]

Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

No problem at all [redacted] I'll do that right now and flick you an email once its updated.

Thanks,

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 12:36 PM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Update and send to me please… [redacted] ..so if you can update and I will review

Thanks

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 10:42 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

I will update the WP2 with the advice from [redacted] but just wanted to check if you had anything you wanted me to change or add before I update the WP2?

Thanks,

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 10:39 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Did you take the advice from [redacted] and incorporate?

[redacted]

From: [redacted]
Sent: Tuesday, 25 June 2019 10:38 AM
To: [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hey [redacted]

Just wondering if you had a chance to look at this recall yet or if you have any feedback or advice before I send it back to [redacted]?

Thanks alot,

[redacted]

From: [redacted]
Sent: Monday, 24 June 2019 5:02 PM
To: Devices Clinical Advice; [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy

Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted] and thanks

I share your concerns, noting that acne sufferers could be on relevant medications.

As the company does not intend to return this device to market, they presumably should not object to it being a Class 1 recall instead of Class 2, but [redacted] may be able to advise.

However, misuse by

Also

"wearing the mask for two or more sessions in one day would exceed the current 2.2 J·cm-2retinal exposure guideline of ANSI Z80.36-2016[3]."

Note the IFU states for use age 12 years and older. There are no instructions that juveniles must be supervised by a responsible adult. The risk of misuse (frequent or prolonged use) by an enthusiastic juvenile is possible.

Sponsor will not know which customers have bought the device (sold through chemists with no medical practitioner supervision), so cant do letter to patient customers.

They should do an advert in paper though for patients to return device to the point of sale for a refund.

I note only 30 doses per mask, so if recall now, patients should not be exposed after 1 to 2 months of use so should not be long term risk of access to the device.

Cheers

[redacted]
Devices Clinical Section | Medical Devices Branch
Medical Devices & Product Quality Division
Therapeutic Goods Administration | Health Products Regulation Group
Australian Government Department of Health
T: [redacted] | **M:** [redacted] **E:** [redacted]@health.gov.au
Site: [redacted] | 136 Narrabundah Lane, Symonston, ACT, 2609
Post: PO Box 100, Canberra ACT 2601, Australia
Mail Drop Point: Symonston #122
[redacted]

From: Devices Clinical Advice
Sent: Monday, 24 June 2019 3:56 PM
To: [redacted]
Cc [redacted]
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Good afternoon [redacted] and [redacted]

I have completed the WP2 for this recall (it is filed in trim : D19-5680162) and also made some changes to the retail and wholesale letter. Would appreciate your review and to see if you agree with my advice and proposed up-classification to a Class 1 and for a consumer level recall. Also whether you think the amendments to the retail and wholesale letters are appropriate or if there is anything extra we should include. Not sure what other advice I should offer in terms of the proposed recall action (Consumer recall and web statement) or what advice you have on what I have written in the WP2.

[redacted] located an IFU for the device at https://www.neutrogena.com/on/demandware.static/-/Library-Sites-JNJSharedLibrary/default/dwd15e356f/other/IFU%20US%20acne%20mask%2023OCT2018.pdf

Relevant TRIM docs:

TRIM File: E19-581096

WP2: D19-5680162
HHE: D19-5669938
Retail Letter: D19-5669941
Wholesale Letter: D19-5669942
Further info/background: D19-5669933
Thanks in advance for your feedback and advice,

Regards,
[redacted]

From: [redacted]
Sent: Monday, 24 June 2019 1:50 PM
To: Devices Clinical Advice
Subject: RE: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hey [redacted]
Yes as per the roster (see attached from our sharepoint site) when you do SAS you do Recalls so if you are covering [redacted] you cover both.
Review the recall and send me your WP2 completed form for us to review.
Cheers
[redacted]

From: Devices Clinical Advice
Sent: Monday, 24 June 2019 1:27 PM
To: [redacted]
Subject: FW: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]
Just after noticing this come in - not sure whether I'm covering recalls today too with [redacted] being away or just SAS – let me know if you need me to look at the below recall.

Thanks,
[redacted]

From [redacted]
Sent: Monday, 24 June 2019 12:50 PM
To: Devices Clinical Advice
Subject: Recalls - Class 2 - RC-2019-RN-00986-1 - Neutrogena Visibly Clear Light Therapy Acne Mask and Activator - Recall [SEC=OFFICIAL]

Good Afternoon Device MOs,
We have received a proposed class III retail level recall for the Neutrogena Visibly Clear Light Therapy Acne Mask and Activator. I have assessed this as a class II (per the subject line) as there is a risk of harm for a subset of the population.
Would appreciate some input, particularly regarding the classification and level of the action.
For your reference, I believe I have located an IFU for the device at https://www.neutrogena.com/on/demandware.static/-/Library-Sites-JNJSharedLibrary/default/dwd15e356f/other/IFU%20US%20acne%20mask%2023OCT2018.pdf
Notably: page 8 of the HHE states that "foreseeable misuse for the NLTAM currently on the market was defined as: staring directly at the LEDs; or more than 10 min exposure per day" – there are no precautions to this effect in the IFU per the Essential Principles (the closest would be page 12 of the IFU that states "use the mask once daily").

Relevant TRIM docs:
TRIM File: E19-581096
WP2: D19-5680162
HHE: D19-5669938
Retail Letter: D19-5669941
Wholesale Letter: D19-5669942
Further info/background: D19-5669933
I've also sent an email with a few additional questions to J&J (D19-5669942) for them to get back to us in the meantime.
Cheers,

[redacted]
Recalls Section | Manufacturing Quality Branch | Medical Devices and Product Quality Division
Phone: [redacted] | Fax: [redacted] | Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [redacted] [CONAU]
To: Recalls
Cc: [redacted] [JJPAU]; [redacted] [JJPAU]
Subject: RE: Customer list clarification required - Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]
Date: Monday, 24 June 2019 11:28:00 AM
Attachments: Updated List of wholesalers AU 240619.xls

Hi [redacted]

Thankyou for your email, regarding the below customer entries, these were inadvertently included in error as these are actually marketing agencies that had requested samples of the product to be photographed for catalogues. Apologies for this! These have now been removed from the list. Please find attached revised list.

Kind regards,

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

From: [redacted] <[redacted]@health.gov.au> **On Behalf Of** Recalls
Sent: Friday, 21 June 2019 4:58 PM
To: [redacted] [CONAU] [redacted]@its.jnj.com>
Cc: [redacted] [JJPAU] [redacted]@ITS.JNJ.com>; [redacted] [JJPAU] <[redacted]@ITS.JNJ.com>
Subject: [EXTERNAL] Customer list clarification required - Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=OFFICIAL]

Dear [redacted]

Thank you for the documentation, this will be assessed by the Recalls coordinator and we will be in contact in due course.

In relation to your customer list, please provide additional information as follows:

[redacted]	[redacted]	Please advise if this is a sale to an individual, or provide the company name
ATT: [redacted]		Please advise if this is a sale to an individual, or provide the company name
[redacted]		Please advise if this is a sale to an individual, or provide the company name
[redacted]		Is this entry a duplication of Sencom Visual Communications?

In addition, please confirm there are no records in relation to the cash sales made from JJP.

Kind Regards,

Recalls Section
Manufacturing Quality Branch

Phone: [redacted]
Fax: [redacted]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100

Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted] [CONAU] [mailto:[redacted]@its.jnj.com]
Sent: Friday, 21 June 2019 3:55 PM
To: Recalls
Cc: [redacted] [JJPAU]; [redacted] [JJPAU]
Subject: Attention [redacted]- Neutrogena Visibly Clear Light Therapy Acne Mask [SEC=No Protective Marking]
Importance: High

Dear [redacted]

Thank you for the phone conversation yesterday afternoon regarding our NEUTROGENA® Visibly® Clear Light Therapy Acne Mask and activator that Johnson & Johnson Pacific (JJP) would like to conduct a voluntary Class III recall from wholesalers and retailers.

Background information

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask on the eye. Out of an abundance of caution, we have made the voluntary decision to recall the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator at the wholesale and retail levels. We have initiated a global stop-ship on this product and the activator.

Description of device and its intended application

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of Red and Blue light via light-emitting diodes (LEDs), and weighs less than 400g.

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator is offered separately to increase the number of doses available from the Neutrogena® Visibly Clear® Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries**.**

Description and justification of the action

Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask are rare, generally mild and transient.

- For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury (further details are described in the Health Hazard Evaluation attached).
- It is predicted that users and misusers in this population would almost certainly develop intense light sensitivity and aversive symptoms (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in colour vision, abnormal visual acuity) with any use of the Mask, making further use self-limiting.
- The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is safe for use by the general population when used as directed.

Corrective action

Corrective action is not applicable as this model of the NEUTROGENA® Visibly Clear Light Therapy Acne Mask and activator will be discontinued globally for commercial reasons.

The following documentation is attached for your reference:

- ARTG entry
- HHE
- DRAFT customer (wholesaler), retailer letters and acknowledgment form
- Customer list – as per our phone conversation we have included the full list of wholesalers. Retailer information is difficult to obtain as it is owned by the wholesalers

We look forward to hearing from you on this matter. Please note [redacted] and my manager, [redacted] will be the key contact. Please feel free to reach out to myself or my manager [redacted]@ITS.JNJ.com) with any questions.

Kind regards,

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

[redacted]
Johnson & Johnson Pacific PTY LTD
45 Jones Street Ultimo 2007
PH [redacted]

Record Summary

287825 Johnson & Johnson Pacific Pty Ltd - Red/blue light phototherapy unit

Sponsor	Johnson & Johnson Pacific Pty Ltd
Therapeutic Type	Medical Device
Product Category	Included Class IIa
ARTG Start date	12/04/2017
Postal Address	Locked Bag 5, BROADWAY, NSW, 2007 Australia
Billing Address	Locked Bag 5, BROADWAY, NSW, 2007 Australia

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Certificate number(s)
Johnson & Johnson GmbH	Johnson & Johnson Platz 2 , Neuss, 41470 Germany	DV-2017-MC-00391-1

Products

1.Red/blue light phototherapy unit

Product Type	Single Device Product	**Status**	Current
		Effective date	12/04/2017

GMDN	62116 Red/blue light phototherapy unit
Functional description	Not included on record
Intended purpose	An assembly of battery-powered devices intended to emit both red and blue light for the treatment of a facial skin condition by the patient in the home.
Variant information	

Device Information

Record Summary

Specific Conditions

No Specific Conditions included on Record

Record Summary

Office of Consumer Medical Safety
Johnson & Johnson Family of Consumer Companies

Health Hazard Evaluation

NEUTROGENA Light Therapy Acne Mask
Photobiological Effects of Blue Light

This document is a:
☒ Health Hazard Evaluation (HHE) of Product Released for Use in Market or Research
☐ Health Risk Assessment (HRA) of Product Not Released and within Company Control

Version:	v1.0
Date:	18June 2019
Prepared by:	Office of Consumer Medical Safety
Document Name:	*HHE NTG LightTherapyAcneMask Blue Light Photobio Effect v1.0 FINAL 18-Jun-2019*
Location:	https://jnj.sharepoint.com/teams/skillmansafetyteam/Shared%20Documents/Forms/List.aspx

Product Name	NA and EMEA: Neutrogena Light Therapy Acne Mask AP: Neutrogena Visibly Clear Light Therapy Acne Mask
Panel Code	N/A
Product Code	30035782 (NA, EMEA), 26202033 (AP) / 681012400
Model	Model 31000
Lot/Serial Numbers	All lots in market and within J&J control. UDI (DI:00070501101247)
Marketing Status	Active – Marketed in NA, EMEA, AP

Key: AP – Asia Pacific; EMEA – Europe, Middle East, Africa; NA -North America

1. PROBLEM, DEFINITION AND ANALYSIS

1.1. Summary of the Problem

Phototherapy refers to the use of nonthermal, noninvasive light to achieve a therapeutic outcome and can apply to a variety of light-emitting devices. Recent advances in technology have allowed the use of light emitting diodes (LEDs) for the treatment of medical conditions, such as mild-to-moderate acne vulgaris. The Neutrogena Light Therapy Acne Mask (NLTAM) has an array of blue and red LEDs that deliver light to the skin of the face. The NLTAM has shown efficacy in treating acne breakouts. When used as directed or under foreseeable misuse conditions, there is the potential for the eyes to be exposed to the blue light emitted from the LEDs.

Blue light is widely used in electronic devices such as cell phones and computer monitors and has been considered to be safe when used in compliance with regulatory standards. New research has raised questions about the potential relationship between exposure to blue light and retinal damage that could lead to macular degeneration.

Transient visual adverse events (AE) have been reported by NLTAM users with rare frequency. No pattern of visual disturbances of major clinical concern has been observed and the reporting rates of non-serious transient visual adverse events are rare. However, s11C s11C(1)(b), given there is no ocular benefit of blue light exposure, the company further evaluated the potential risks of ocular photobiological exposure.

1.2. Product Information

NEUTROGENA® (NTG) Light Therapy Acne Mask is a reusable, non-invasive, non-thermal, non-sterile product commercialized in United States, Canada, Europe and Australia, where it is classified as a Class II medical device; and most countries in Asia Pacific (APAC) where it is classified as a Commodity. The product first launched in the United States in October 2016.

It is indicated to treat mild to moderate facial acne in males and females 12 years or older.

It is a home-use product that emits blue and red light, to target bacteria that cause mild to moderate acne, and to reduce inflammation.

The product kit consists of an acne face mask and a detachable corded activator. Replacement/refill activators are marketed separately. Each activator is designed to provide 30 ten-minute treatment sessions. The user places the mask over the face and presses the power button – holding for 1 second – to initiate treatment. The acne mask has a continuous working time of 10 minutes and shuts off automatically once complete. This product was designed to be used once a day. Continued use after the initial 30 treatment sessions is recommended to see further improvement and this would require a replacement/refill activator.

Each product kit includes an Instructions for Use (IFU) brochure/insert describing the product and its different components, how it works, who should use it, instructions for use, warnings and precautions, risks, storage and care, and troubleshooting. Images of the product package (front and back) are seen below.

Figure 1: Neutrogena Light therapy Acne Mask package

1.3. Analysis

Root cause of the problem (if known)

No root cause investigation was conducted, as this issue did not arise from a product non-conformance.

[redacted] it was determined that the NLTAM design met all the requirements of [redacted] for LED Lighting Products Standards for Eye and Skin Safety, but owing to the positioning and distance of the lights from the eyes, other safety standards [redacted] should be considered. Based on these insights, it was determined that a modified approach to exposure assessment should also be applied to the NLTAM.

[redacted]

As a result of the modified assessment, it was determined that exposure to blue light from the NLTAM can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in the normal population. In addition, a theoretical potential risk was identified under normal or foreseeable misuse conditions for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity.

Company's estimate of number of units affected

- *How many units from the affected lots are expected to have or develop the defect?*
  As noted above, there is no product non-conformance, or defect. The below tables provide our best estimate of the number of masks and activators of Neutrogena Light Therapy Acne Mask and Neutrogena Visibly Clear Light Therapy Acne Mask in distribution and under Company control, presented by region/country.

Table 1. Number of MASKS in distribution and under J&J control

Region/Country	**Masks** in distribution (units)	**Masks** under J&J control (units)	Total
EMEA	[redacted]	[redacted]	[redacted]
Asia Pacific			
North America - United States			
North America - Canada			
Total			

Table 2. Number of ACTIVATORS in distribution and under J&J control

Region/Country	**Activators** in distribution (units)	**Activators** under J&J control (units)	Total
EMEA	[redacted]	[redacted]	[redacted]
Asia Pacific			
North America - United States			
North America - Canada			
Total			

- *How many units will reach the consumer level, and will the likelihood of harm increase with time? Consider the risk vs. exposure link and if progressive degradation occurs.*
  The numbers of units distributed to market are presented in the tables above.

The effects of exposure when used as directed in normal healthy population will be transient and reversible. In users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders), as well as for users taking medications which could have the potential to enhance ocular photosensitivity, repetitive exposure beyond two doses to the blue light has the potential, in theory, to cause harmful ocular effects. However, it is almost certain that the discomfort caused in this subset of the population would prevent users from subsequent exposure beyond two doses and thereby prevent the ocular harm from occurring (see Section 2. Health Risks and Medical Safety Assessment).

If product failure occurs, does the user easily recognize it?
Not applicable. This issue is not related to a product non-conformance.

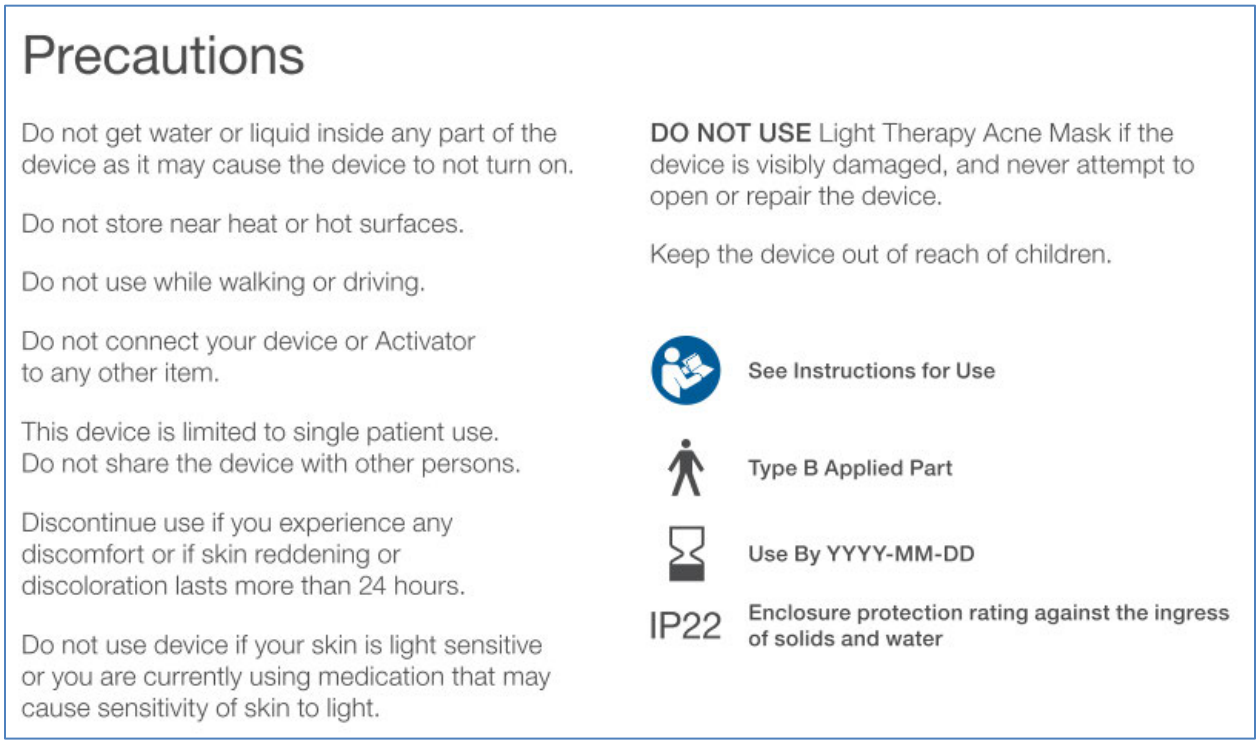
Factors that may contribute to product risk (i.e., product design, manufacturing problems, or user error).
Ocular exposure during use of NLTAM is unintentional. The eye shield included in the mask is not designed to eliminate exposure or fully filter LED light emission.

Factors that might mitigate risk (i.e., product labeling).
At present, the product label/IFU does not contain warnings on potential ocular reactions resulting from product use, but advises consumers to:

- discontinue use if they experience any discomfort, and
- avoid using the device if under treatment with medications that can cause sensitivity to light.

The complete list of precautions for use in the IFU is shown below.

Figure 2. Neutrogena Light Therapy Acne Mask - precautions for use*



** Variation German IFU: "Do not use the device if you are light sensitive or if you are currently taking drugs that could cause a light sensitivity of the skin"*

Does the health consequence have significant public health impact beyond users?
No, there is no health impact beyond the user of the product.

2. HEALTH RISKS AND MEDICAL SAFETY ASSESSMENT

2.1. Exposure Assessment

The company assessed the potential short-term (up to 30 doses) effects and long-term (>1 month up to 5 years) effects of blue light exposure on the retina in association with use of the NLTAM device, in consideration of the intended use, intended users and use environment, and in consideration of foreseeable misuse.

It was determined that the mask design met all the requirements of [redacted] Risk Group), for LED Lighting Products Standards for Eye and Skin Safety, but owing to the positioning and distance of the lights from the eyes, other safety standards [redacted] were considered.

As a result of the modified assessment the investigation determined that blue light exposure from the LED sources in the NLTAM, when used by a subject according to intended-use and consistent with labeling, emit visible light that is well below current guidelines for human

exposure. This conclusion considers all reasonably foreseeable exposure conditions of normal individuals and applies for a single 10-minute (600-s) daily treatment. However, misuse by wearing the mask for two or more sessions in one day would exceed the current 2.2 $J \cdot cm^{-2}$ retinal exposure guideline of ANSI Z80.36-2016[3].

In addition, it was identified that these levels of exposure although appropriate for normal individuals could potentially cause risk to individuals with light-sensitive retinal diseases (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as users taking medications that have the potential to enhance ocular photosensitivity.

The assessment considered the following conditions:

Normal usage: 10 min daily session viewing through the vision slot.

Foreseeable misuse: Foreseeable misuse for the NLTAM currently on the market was defined as:

- Staring directly at the LEDs, or
- More than 10 min exposure/day.

2.2. Risk Characterization Based on Exposure Information

A risk characterization was performed considering the device design (i.e. light power, wavelength, energy, configuration), potential geometries of light exposure, facial features (i.e. eyelids, eyelashes, cheek bones, etc.), aversion responses, photobiological testing conducted, expert review of the current literature and understanding of blue light retinal exposure hazards, and labeling requirements.

The following key factors were included as the basis for the risk evaluation/assessment:

- *Normal Use*: Device used as intended with user looking through viewing slot – 10 min per day
- *Foreseeable Misuse*: Subject stares directly at LEDs or the mask is used more than once per day
- *Acute* was defined as up to 30 doses (maximal use of a single activator), while *Chronic* was defined as daily use from >1 month (30 doses) up to 5 years

This assessment considered exposure to the peripheral retina as per additional testing and indirect illumination of the macula.

[3] American National Standards Institute (ANSI, 2016), *American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments,* ANSI Z80.36-2016, New York, ANSI.

Described below are the potential health consequences, in the normal population and in users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, from use of the NLTAM.

NORMAL POPULATION (Male and Female / 12 years - 25+ years)

a) Normal Use: Device used under normal use conditions (10 min daily treatment time and looking through viewing slot)

1. **Acute:** up to 30 doses
   Temporary (approx. 1 min) adaptation - distorted color vision and/or blurred vision due to tearing.

2. **Chronic:** Device used under normal use conditions (10 min daily treatment time and looking through viewing slot from >1 month (30 doses) up to 5 years)
   Temporary loss of hue perception in blue spectrum (color distortion)

b) Foreseeable Misuse:

1. **User wearing mask more than once daily**
   Temporary loss of hue perception in blue spectrum (color distortion), ocular discomfort, disability glare, after images and headaches, selective chromatic adaptation ("green vision").

2. **User wearing mask - stares directly at LED.**
   Temporary loss of hue perception in blue spectrum (color distortion), ocular discomfort, disability glare, after images and headaches, selective chromatic adaptation ("green vision").

Type of potential exposure considered in normal and foreseeable misuse scenarios: Exposure to peripheral retina and indirect illumination of the macula.

Because of the position of the lower LEDs, the macula is not expected to have direct exposure (indirect illumination of the macula can occur). Duration of exposure is expected to be a fraction of a second as this would likely trigger an aversion response (i.e. blink / close eyes / other).

POTENTIALLY SUSCEPTIBLE POPULATION

No established exposure limits have been identified for blue light in users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders), as well as for users taking medications which could have the potential to enhance

ocular photosensitivity, but the exposure limits would be expected to be lower than in normal subjects.

Potentially susceptible populations include persons with these disorders:

- Retinitis Pigmentosa
- Ocular Albinism
- Photosensitive Medication
- Other Hereditary Ocular Disorders.

The theoretical harms defined for potentially susceptible populations cover a heterogenous group with varying clinical severity and risks. The theoretical harms are based on extrapolations of what is known about potential effects of intense light in some of these groups. It is a worst-case scenario extrapolation that considers the most severe of cases, based on data using other light sources that may not be directly applicable to the exposure conditions of the NLTAM. Moreover, there is no evidence in post-marketing surveillance of any risk of permanent harm and the incidences of transient light effects are rare. It is almost certain that use will be self-limiting after 1-2 uses in users with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity because of the prolonged and transient effects described, and therefore it is almost certain that no permanent damage would occur from devices that are in the market.

a) Normal Use: device used as directed (10 min daily session looking through the viewing slot)

Up to 2 uses

Initial (up to 2 uses) - Prolonged (hours) and transient color adaptation and/or potential for prolonged and transient loss in hue perception in blue spectrum (color distortion). Intense discomfort to light as well as prolonged but transient adaptation defects – translated into visual acuity and light sensitivity. It is almost certain that this discomfort will prevent subsequent exposure beyond initial use.

More than 2 uses

Small subset / Rare Population - Repeated exposure beyond two uses may cause varying degrees of retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss. As noted above it is highly unlikely that repeat exposures beyond two uses would occur in these users as it is almost certain that discomfort caused in this subset of the population would prevent consumers from subsequent exposure beyond 2 doses and thereby prevent the ocular harm from occurring.

b) Foreseeable misuse:

- **User wearing mask -** Stares directly at LED. For this condition the device is used for 10 min daily.

  Initial (up to 2 uses) - Prolonged (hours) and transient color adaptation and/or potential for prolonged and transient loss in hue perception in blue spectrum (color distortion). Intense discomfort to light as well as prolonged but transient adaptation defects – translated into visual acuity and light sensitivity.

  Repeated exposure beyond two uses may potentially cause varying degrees of peripheral retinal damage that could be irreversible and could accelerate peripheral vision impairment or loss. As noted above it is almost certain that these users would not have repeat exposures beyond two uses due to discomfort experienced during initial 1-2 uses.

  Because of the position of the lower LEDs, the macula is not expected to have direct exposure (indirect illumination of the macula can occur). The duration is expected to be a fraction of a second as this would likely trigger an aversion response (i.e. blink / close eyes / other).

- **Device used looking through viewing slot more than 10 min/day:**

  Repeated, consecutive exposure in a single day has the potential to cause varying degrees of retinal damage that can be irreversible and could accelerate peripheral vision impairment or loss. As noted above it is almost certain that these repeat exposures (particularly consecutive, repeat exposures) would not occur in these users since the discomfort in this subset of the population would prevent consumers from subsequent exposure.

2.1.1. Characterization of susceptible population

It is difficult to characterize the population with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity as it encompasses a heterogenous group with varying clinical stages and risks.

The following describes some medical conditions that may place some users at potential risk compared to the normal healthy population.

Retinitis Pigmentosa

Retinitis pigmentosa (RP) is a group of genetic disorders characterized by progressive retinal degeneration and dysfunction, affecting primarily photoreceptor and pigment epithelial function.[4] It may occur alone or as part of a syndrome. A family history of RP is present in approximately 70% of patients. The worldwide prevalence of RP is estimated at 1 in 4000 to 5000. [5]

The most common form of RP presents with symptoms restricted to the eye (ie, non-syndromic RP). Multi-organ involvement is seen in syndromic forms of RP, such as Usher Syndrome, where a patient can present with congenital or early-onset hearing impairment followed by the development of RP.[5]

Ocular symptoms of RP arise from loss of retinal rods and cones. Common manifestations include night blindness and loss of peripheral vision.[6] Visual acuity is variably affected. Other symptoms reported by patients include photopsias (sensations of sparkling lights) and headache.[7] Other ocular abnormalities that may occur with RP are astigmatism, myopia, and changes in visual acuity and color vision.

The clinical presentation of RP is variable, with some patients experiencing visual loss during childhood while others remaining asymptomatic until adulthood. The natural course of the RP is gradual loss of visual field, visual acuity, and electroretinographic activity over time. Due to the narrowing of visual fields, the majority of patients meet criteria for legal blindness by age 40.[8]

Ocular Albinism

Ocular albinism is a genetic condition that reduces the pigmentation of the iris and retina, resulting in severe impairment of visual acuity (loss of sharpness of vision) and problems

[4] Retinitis pigmentosa. A symposium on terminology and methods of examination. Ophthalmology 1983; 90:126.
[5] Syndee Givre, MD, PhDSeema Garg, MD, PhD. Retinitis pigmentosa: Clinical presentation and diagnosis. UpToDate 31-Oct-2017.
[6] Weleber RG, Gregory-Evans K. Retinitis Pigmentosa and Allied Disorders. In: Retina, Ryan SJ (Ed), Elsevier Mosby, 2006. p.395.
[7] Heckenlively JR, Yoser SL, Friedman LH, Oversier JJ. Clinical findings and common symptoms in retinitis pigmentosa. Am J Ophthalmol. 1988;105(5):504.
[8] Hartong DT, Berson EL, Dryja TP. Retinitis pigmentosa. Lancet. 2006;368(9549):1795.

with stereoscopic vision (inability to perceive depth). Unlike other forms of albinism, ocular albinism does not significantly affect the hair/skin color.[9]

The most common type of ocular albinism is ocular albinism type 1 (OA1) or X-linked ocular albinism, resulting from inherited X-linked mutation of GPR143 gene.[10] The prevalence of ocular albinism has been reported to be one male in 20,000 live births. Affected males present with vision abnormalities at birth, which do not worsen with time. Apart from vision loss, patients may present with nystagmus (involuntary eye movement), strabismus (crossed eyes), and sensitivity to light (photophobia). Patients may also present with foveal hypoplasia and abnormalities in the optic nerve.[10]

2.3. Post-marketing Safety Review and Surveillance

NTG Light Therapy Acne Mask Adverse Event (AE) cases received globally from launch through 06 November 2017 were fully processed in the [redacted] Thereafter, the cases received globally were received and continued to be assessed and processed in the [redacted] Both systems were searched, and data was reviewed in aggregate in order to obtain a comprehensive global overview.

[redacted]

A search of the [redacted] database was performed for all cases that met the following criteria:

- Product Family Names (PFN):
  - NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 0443AP
  - NEUTROGENA LIGHT THERAPY ACNE MASK REFILL ACTIVATOR AP 0443AAP
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT ACTIVATOR EU 3LTCACEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT EU 3LTAKIEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE MASK EU 3LTCMAEU
  - NTG LIGHT THERAPY ACNE MASK CAN NTLTAMCA
  - NTG LIGHT THERAPY ACNE MASK USA NTLTAMUS
- MedDRA System Organ Class (SOC): Eye Disorders, Nervous System Disorders
- Product role: Suspect or Interacting
- Region/country: Global

[9] U.S. National Library of Medicine. Ocular albinism. Available at: https://ghr.nlm.nih.gov/condition/ocular-albinism#inheritance

[10] National Organization for Rare Disorders. Rare Disease Database - Ocular Albinism. Available at: https://rarediseases.org/rare-diseases/ocular-albinism/

- Case type: Spontaneous, Solicited, Clinical, or Medical Literature
- Date: cumulative cases received up to 06 November 2017
- Case status: Closed

[redacted]

A search of the [redacted] database was performed for all cases that met the following criteria:

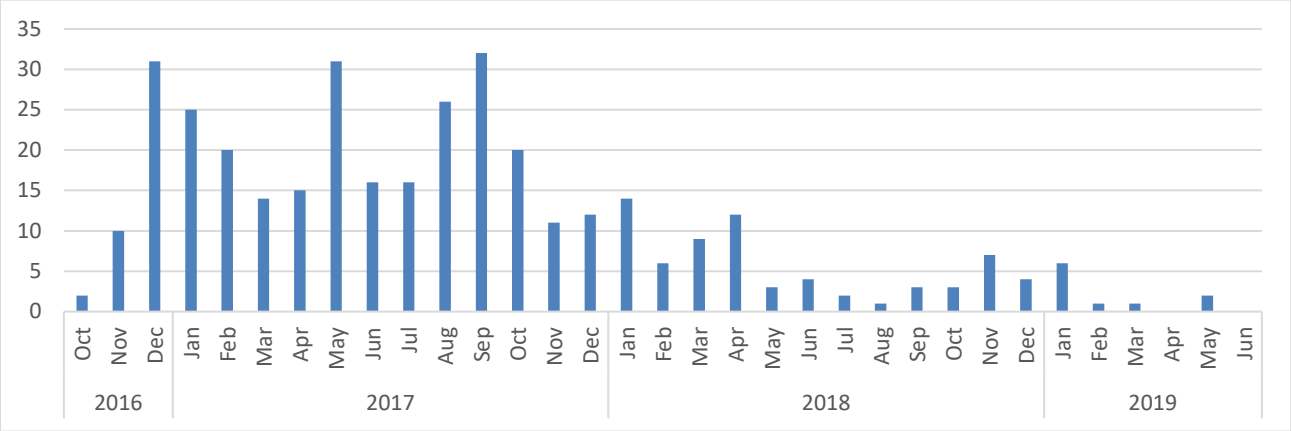
- Product Family Names:
  - NEUTROGENA LIGHT THERAPY ACNE MASK KIT AP 0443AP
  - NEUTROGENA LIGHT THERAPY ACNE MASK REFILL ACTIVATOR AP 0443AAP
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT ACTIVATOR EU 3LTCACEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT ACTIVATOR EU 3LTRACEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE KIT EU 3LTAKIEU
  - NEUTROGENA VISIBLY CLEAR LIGHT THERAPY ACNE MASK EU 3LTCMAEU
  - NTG LIGHT THERAPY ACNE MASK CAN NTLTAMCA
  - NTG LIGHT THERAPY ACNE MASK USA NTLTAMUS
- Case Category Level 3: Neurological Disorder/Disturbance; or Visual Disorder/Disturbance
- Region/country: Global
- Date: Cases received after 06 November 2017 through 13 June 2019

2.3.1. [redacted] and [redacted] database search results for visual/eye signs & symptoms

A total of 359 cases of visual/eye signs or symptoms were extracted from both [redacted] and [redacted] databases received through 13 June 2019. The majority of them were assessed as non-serious (98.05%; 352). Seven were assessed as serious (1.95%).

The graph below represents the monthly distribution of all cases of visual/eye signs or symptoms for the period in scope (Figure 3). The cases and trends are discussed further in the succeeding subsections.

Figure 3: Monthly distribution of all cases of visual/eye signs and symptoms associated with Neutrogena Light Therapy Acne Mask through to 13 June 2019.



Serious cases under Eye Disorder System Organ Class (SOC):

A total of 7 serious cases were identified under Eye Disorders SOC. One case [redacted]) pertained to a consumer who experienced sudden temporary vision loss (5 seconds), light sensitivity and headache after using the light therapy mask. This consumer was later diagnosed with idiopathic endocranial hypertension. This case is also included in the section on neurological disorders below.

The remaining 6 cases (see details below) described either retinal injury or visual disturbances (i.e. visual impairment, alleged blindness NOS; refractive error; light sensitivity and vision loss) which were attributed by the consumers, either directly or indirectly, to the effects of the light. However, none of the serious cases were confirmed as causally associated with the light exposure as most of these cases presented concomitant clinical conditions that provided more plausible alternative explanations. Moreover, none of these cases showed evidence of having conditions consistent with the potentially susceptible population and none of the visual disturbances were specifically associated with peripheral retinal damage.

- 2 cases described alleged **retinal injury or detachment**: 1 case ([redacted]) was received via social media and provided limited information precluding meaningful medical assessment while the other ([redacted]) was confounded by a history of autoimmune retinal disease which provides a more plausible alternative explanation.
- 1 case ([redacted]) pertained to alleged **corneal damage** with dryness of the eye and impaired vision, where the treating physician was uncertain about a causal relationship.
- 1 case ([redacted]) of alleged **blindness** was received via social media and provided limited information precluding meaningful medical assessment.
- 1 case [redacted]) described an asymptomatic adolescent who was advised that she required reading glasses during a regular check-up. In this case, the **refractive error** was assessed to most likely be a concomitant condition instead of the effect of 1-month of product use.

- 1 case ([redacted]) pertained to an adult consumer who used the product despite being advised by a Company representative that this product is not for use by those with light sensitivity. Causal association of product use with **loss of vision and light sensitivity** is confounded by the consumer's medical history (eye surgery 2 years prior to device use and events that have been regularly occurring with every light exposure.)
- 1 case ([redacted]) pertained to an 18-year-old consumer who experienced **sudden temporary vision loss (5 seconds), light sensitivity and headache** after using the light therapy mask. Best corrective vision at examination was 20/20. Ophthalmological evaluation showed papilledema; macula with no retinal pigment epithelial changes nor retinopathy. The brain CT scan was unremarkable. Final diagnosis was **idiopathic intracranial hypertension.** At follow up patient remained with light sensitivity, headaches and papilledema. Despite a temporal relationship with patient's symptoms, concomitant intracranial hypertension provides a more plausible explanation.

Non-Serious cases under Eye Disorder SOC:

The review of non-serious cases identified ~20% of cases pertaining to users who directly associated the reported events with the lights of the device, with some reporting that the eye shield did not help or that they experienced events even with their eyes closed.

The majority of non-serious cases described reactions that were associated with/may be attributed to light that is perceived as too bright: eye pain, eye discomfort, eye irritation, tearing, blinding, blurring of vision, seeing spots/flashes, and unspecified changes in vision. Forty-percent (40%) of the cases reported changes in vision color, mostly green, while others described other colors, combinations of colors, or unspecified tint in vision.

Events were generally mild and transient. No pattern of adverse events of major clinical concern was identified.

Eye discomfort and blurred vision as well as distorted colors are already outlined as potential risks through light exposure (FM-022680 rev 5) from the NLTAM and are expected to be transient and mild in nature as observed in reviewed cases.

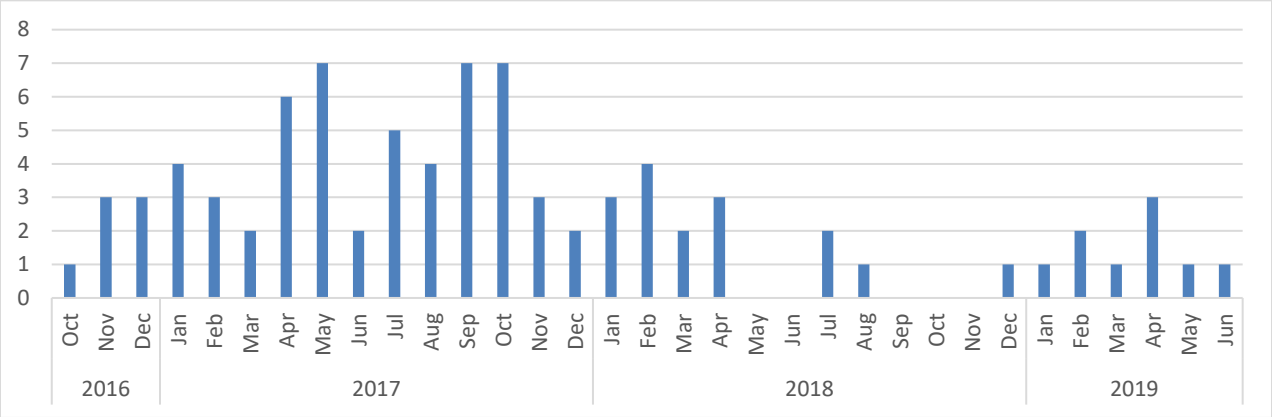
Foreseeable misuse:

A search of all cases in scope of the report identified 2 cases where the consumers used the mask beyond the labeled duration or frequency. The IFU indicates that the product should be used daily, once a day for 10-minutes. One consumer reportedly used the mask 7 times in less than one week and reportedly experienced dry and irritated eyes. Another consumer used the mask twice in a day and reported eye pain and light sensitivity. Both cases were assessed as non-serious.

2.3.2. RSS and PQMS database search results for neurologic disorders

The graph below represents the monthly distribution of all cases of neurologic signs or symptoms for the period in scope (Figure 4). The cases and trends are discussed further in the succeeding subsections.

Figure 4: Monthly distribution of all cases of neurologic signs and symptoms associated with Neutrogena Light Therapy Acne Mask through to 13 June 2019



A total of 85 cases received from October 2016 to June 2019 described neurologic signs or symptoms, where 35 (41.18%) of the consumers attributed these to the light exposure. Overall reporting rate for neurologic signs or symptoms was very rare.

There were 3 (3.53%) cases assessed as serious due to medical significance, reporting optic neuritis (n=1), seizure (n=1), and intracranial hypertension (n=1). None of the reported serious cases are in scope of the blue light potential retinal hazard in this health hazard evaluation and as such are not described further here.

Review of the 80 non-serious cases showed that the majority (66/80; 82.50%) reported headache with or without other associated signs or symptoms such as dizziness, eye pain or blurring of vision. All the events described were clinically mild and transient. Review of cases did not identify a pattern of adverse events of major clinical concern or requiring clinically meaningful interventions.

3. SHIPMENT DATA AND REPORTING RATE (RR)

From October 2016 to May 2019, the product was marketed in 3 regions: North America, Europe/Middle East/Africa, and Asia Pacific. Overall, [redacted] mask kits and [redacted] activator refills were shipped.

The RR was calculated as follows: # of cases per period ÷ Units distributed per period × 1,000,000.

Reporting frequencies are classified according to the CIOMS Working Group[11].

Very common	≥ 1/10	(≥ 100,000 per million units sold)
Common	≥ 1/100 and <1/10	(>10,000 and < 100,000 per million units
Uncommon	≥ 1/1000 and <1/100	(≥ 1,000 and < 10,000 per million units
Rare	≥ 1/10000 and <1/1000	(≥ 100 and < 1,000 per million units sold)
Very Rare	<1/10000	(< 100 per million units sold)
Not known	**(cannot be estimated from the available data)**	

The table below shows the estimated number of units shipped for each region and globally for the Neutrogena Light Therapy Acne Mask and Neutrogena Light Therapy Acne Mask Refill Activator (Table 3).

Table 3: Regional and global shipment data for Neutrogena Light Therapy Acne Mask and Neutrogena Light Therapy Acne Mask Refill Activators from October 2016 to May 2019.

Region	Number of MASK KIT units shipped	Number of ACTIVATOR units shipped
United States	[redacted]	[redacted]
Canada		
Europe, Middle East, Africa (EMEA)		
Asia Pacific		
Global		

For the purpose of this report, the reporting rate calculations take into consideration that adverse events are mostly reported in relation to the mask. In fact, there were only 2 cases (1 report of headache, 1 report of tearing) reported for the activator. For this reason, only the shipment data for the mask was used in the calculation of reporting rates. [NOTE: For pragmatic reasons, the 2 cases reported for the activator were included in the case count used to calculate the reporting rate.]

The table below shows the reporting rates and corresponding CIOMS classification for each region and globally, for cases of eye reactions and neurological disorders associated with Neutrogena Light Therapy Acne Mask (Table 4). The reporting rates for each region as well as for that for the global portfolio were classified as Rare for eye reactions and Very rare to Rare for neurological events.

[11] Guidelines for Preparing Core Clinical Safety Information on Drugs - Report of CIOMS Working Group III. Geneva, WHO, 1995 (Chapter 5, Good Safety Information Practices).

Table 4: Regional and global reporting rates for eye and neurologic cases (exclusively) associated with Neutrogena Light Therapy Acne Mask from October 2016 to May 2019.

Region	Reporting rate for eye reactions (per million units shipped)	CIOMS Classification	Reporting rate for neurologic disorders (per million units shipped)	CIOMS Classification
United States	185.07	Rare	37.91	Very rare
Canada	255.20	Rare	116.00	Rare
Europe, Middle East, Africa (EMEA)	298.11	Rare	79.50	Very rare
Asia Pacific	356.14	Rare	89.04	Very rare
Global	210.24	Rare	48.02	Very rare

4. CONCLUSION

Available data, additional testing, extrapolations using other light sources and expert opinion informed our risk assessment which defined acute and chronic worst-case scenarios including intended use in the normal population and those with certain underlying ocular disorders or taking medications which could have the potential to enhance ocular photosensitivity, and with foreseeable misuse.

Intended Use in the Normal Population

When used as directed, the Neutrogena Light Therapy Acne Mask meets Health Authorities' requirements for normal acute use in a healthy normal population outlined by [redacted] for LED Lighting Products Standards for Eye and Skin Safety.

Post-marketing data suggest that some users in the normal population develop mild reversible and transient adverse effects (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in color vision). No pattern of major clinical concern was identified for these events. Moreover, no serious adverse events deemed causally related to the mask were identified.

Foreseeable Misuse in the Normal Population

s11C(1)(b) [redacted], it was determined that the mask design met all the requirements of [redacted] for LED Lighting Products Standards for Eye and Skin Safety, but owing to the positioning and distance of the lights from the eyes, other safety standards [redacted] were considered. Based upon these insights it was determined that a modified approach to exposure assessment should also

be applied to the NLTAM. As a result of the modified assessment our investigation determined that exposure to blue light from the NLTAM can potentially exceed the current ocular exposure limits under foreseeable misuse conditions in normal populations.

Two specific foreseeable misuse conditions were evaluated: 1) two or more consecutive treatments 10 min each in a single day while the user is looking through the eye slot, and 2) intentional fixation of gaze on the LEDs during a single 10 min treatment. In both of these situations there is the risk that the peripheral retina could be exposed to more than the calculated daily limit of blue light. Potential harms of this misuse in the normal population include temporary loss of hue perception in the blue spectrum (color distortion) which is expected to be minor in severity. It should be noted that intentional fixation on the LEDs would be expected to be self- limiting due to the brightness of the lights and the normal aversion response and importantly that retinal exposure in this situation would be expected to be well outside the area of central vision and not expected to affect the macula.

Post-marketing data suggest that some users in the normal population may use the NLTAM more often than once daily, but no serious ocular effects were reported in association with this misuse.

Intended Use OR Foreseeable Misuse in those with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity

The safe threshold for blue light exposure has not been well-established for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, but it is expected to be lower than in normal subjects.

It is predicted that users and misusers in this population would almost certainly develop intense light sensitivity and aversive symptoms (e.g. eye pain, eye irritation, blurring of vision, seeing spots/flashes, changes in color vision, abnormal visual acuity) with any use of the NLTAM, making further use self-limiting.

Should they continue to use the mask in the presence of aversive symptoms, there is a theoretical risk in a very small subset that varying degrees of peripheral retinal damage could occur and that for some this injury could be irreversible and accelerate peripheral vision impairment or loss. As mentioned above, this potential risk of permanent retinal injury in this population is mitigated by the assessment that it is almost certain that initial use of the mask will be self-limiting due to the aversive signs and symptoms and therefore it is highly unlikely that any permanent damage would occur from use of masks that are in the market.

There are no reports in the company's safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users.

CONTRIBUTORS:

[redacted]

SIGNATURES

AUTHOR

I have reviewed this report and confirm that, to the best of my knowledge, it accurately describes the data available to date:

[redacted] Date

[redacted]

Office of Consumer Medical Safety

APPROVER

I have read this report and, based on the data as presented, agree with the conclusions drawn:

[redacted] Date

[redacted]

Office of Consumer Medical Safety

Annex 1: Framework for Assessment of Severity and Probability of the Adverse Health Consequences

Assess the Probability that Use of, or Exposure to, Product under Recall evaluation will Cause Adverse Health Consequences

	Serious Adverse Health Consequences		Medically Reversible or Transient Adverse Health Consequences	
	Overall Population Using Device	**Population at Greatest Risk**	**Overall Population Using Device**	**Population at Greatest Risk**
Very Common[1] (Every Time[2])	☐	☐	☐	☒[3]
Common[1] (Frequent)	☐	☐	☐	☐
Uncommon[1] (Infrequent)	☐	☐	☐	☐
Rare[1] (Reasonable Probability that Use will Cause[2])	☐	☐	☒[4]	☐
Very Rare[1]	☐	☐	☐	☐
Remote (Remote Probability that Use will Cause[2])	☐	☐	☐	☐
Improbable (Not Likely that Use will Cause Any Adverse Events[2])	☒	☒[5]	☐	☐

[1] CIOMS Working Group III [2] FDA CDRH HHE/HRA Form

[3] These are theoretical adverse events for users with certain underlying ocular disorders (e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders) as well as for users taking medications which could have the potential to enhance ocular photosensitivity, and are based on extrapolations of what is known about the potential effects of intense light in this population. There are no reports in the company's safety database associated with the NLTAM that identify individuals with these underlying ocular disorders.

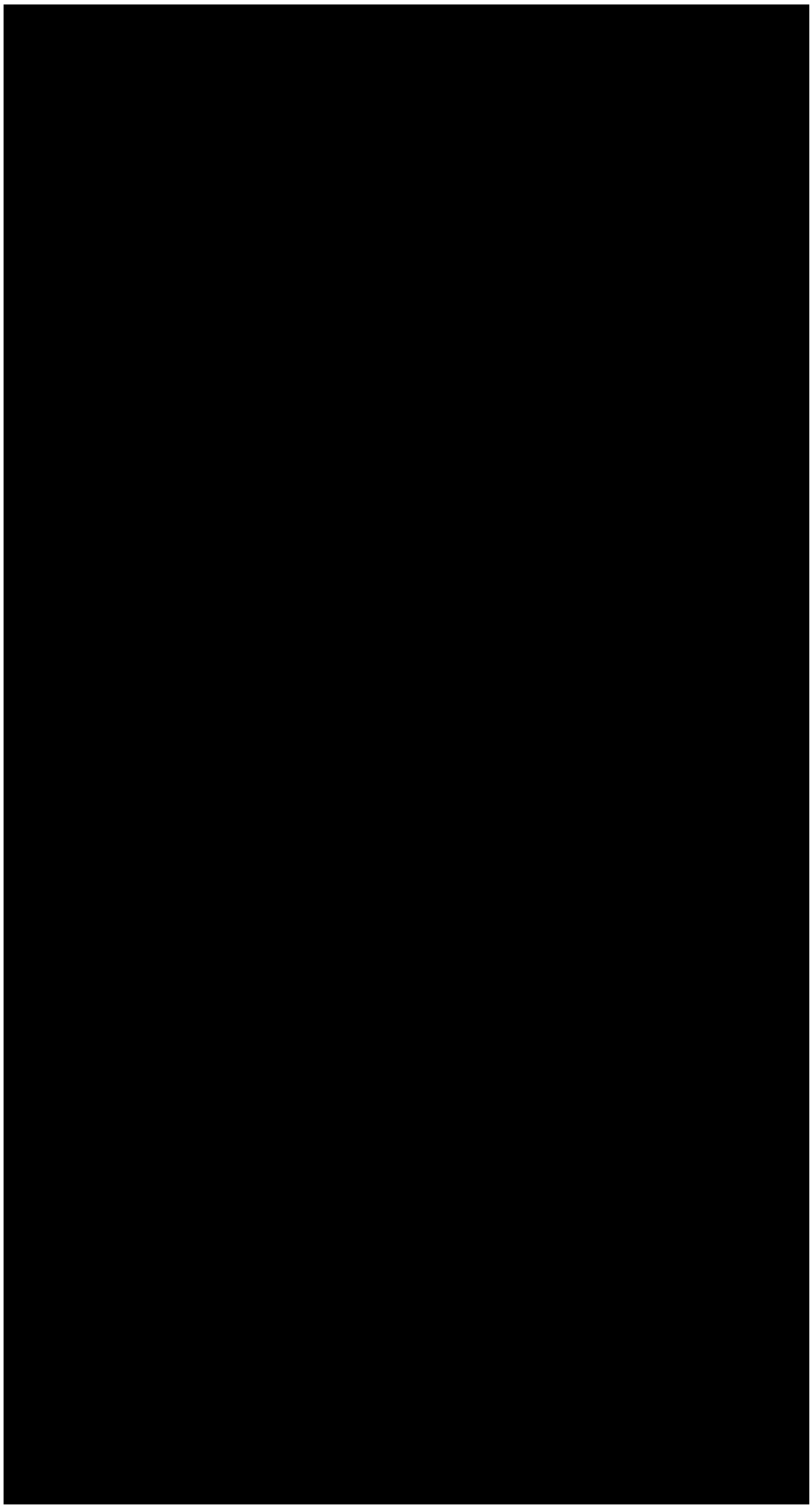
[4] **Based on post-marketing safety data**

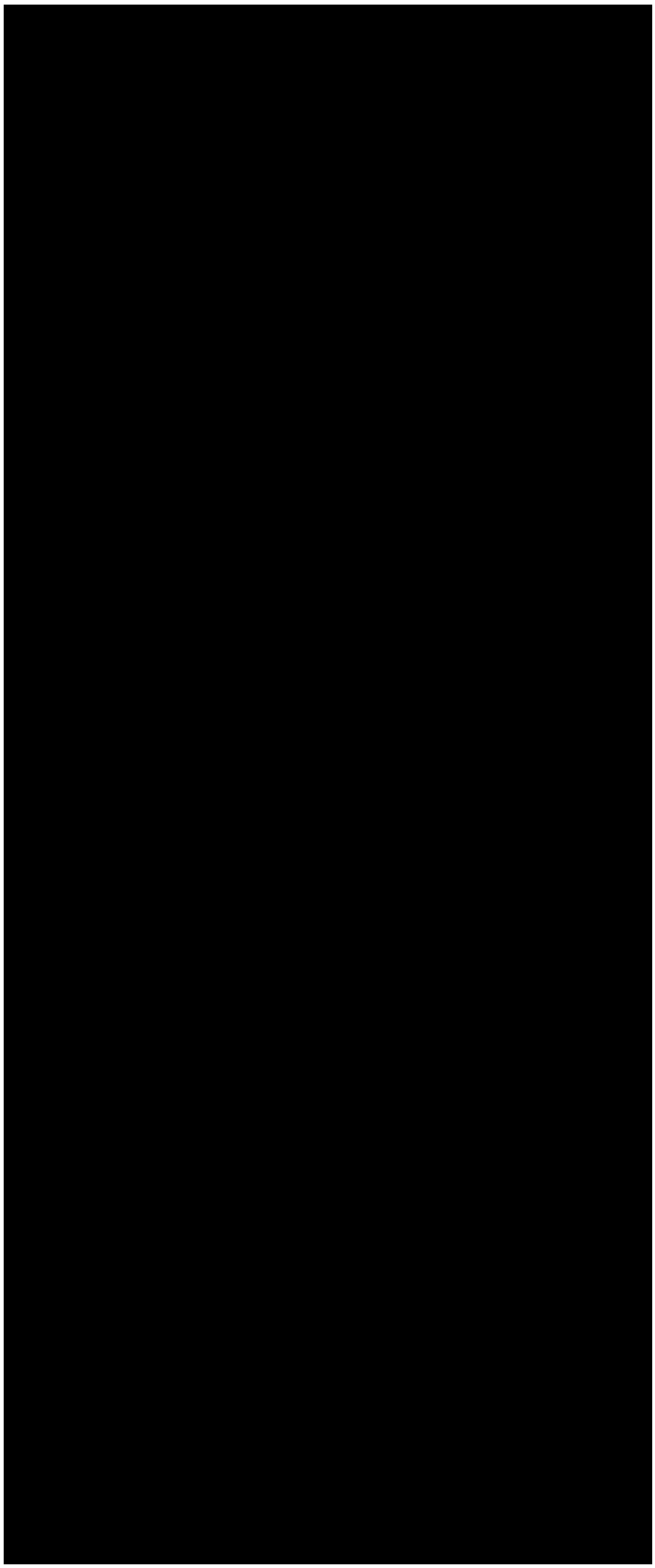
[5] This theoretical risk of permanent retinal injury is mitigated by the assessment that it is almost certain that initial use of the mask will be self-limiting due to aversive signs and symptoms and therefore it is extremely unlikely that any permanent damage would occur from use of masks that are in the market. There are no reports in the company's safety database associated with the NLTAM that identify individuals with these underlying ocular conditions or suggest that permanent ocular injury has occurred in this hypothetical subset of users

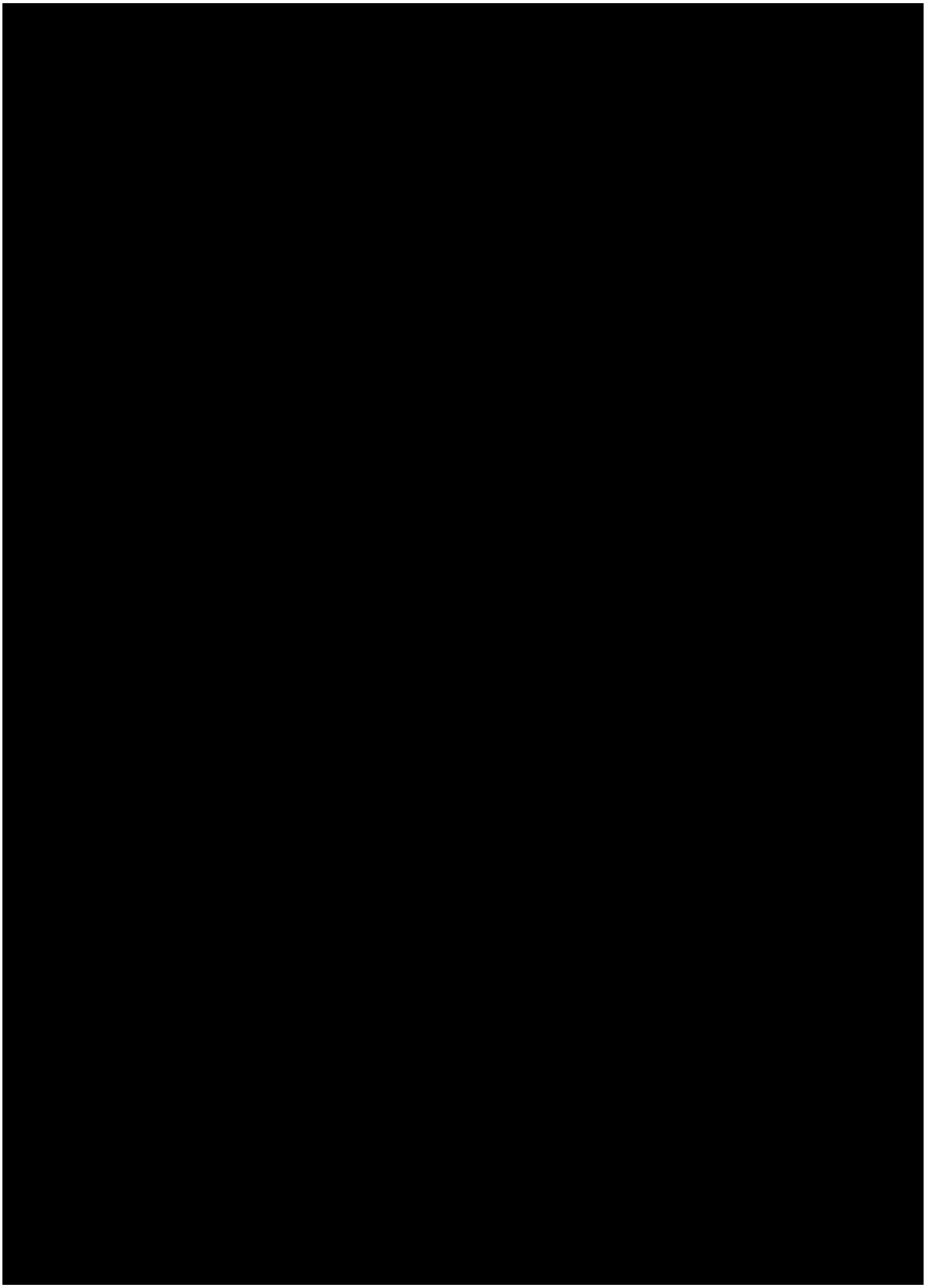
References

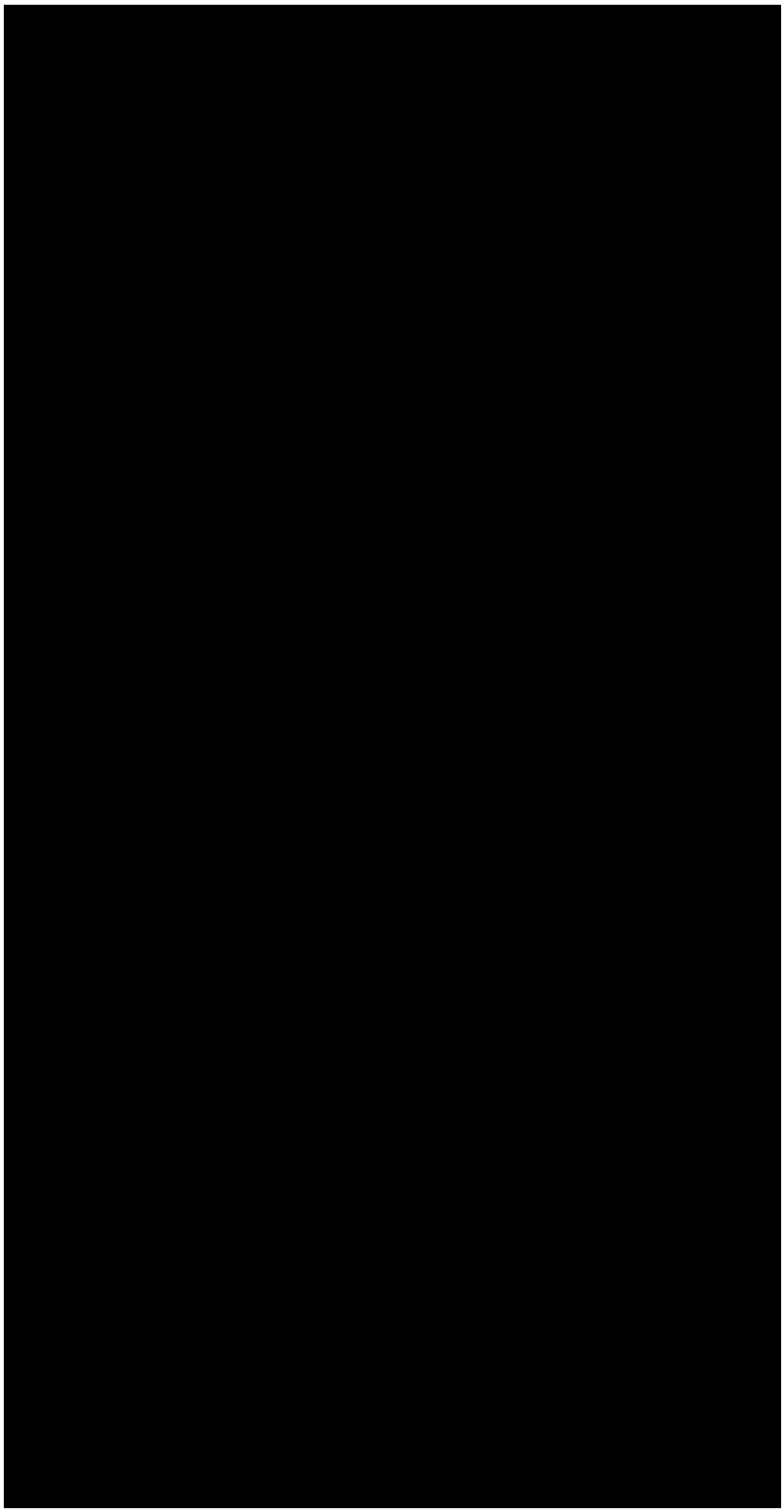
1. Guidelines for Preparing Core Clinical Safety Information on Drugs - Report of CIOMS Working Group III. Geneva, WHO, 1995 (Chapter 5, Good Safety Information Practices).

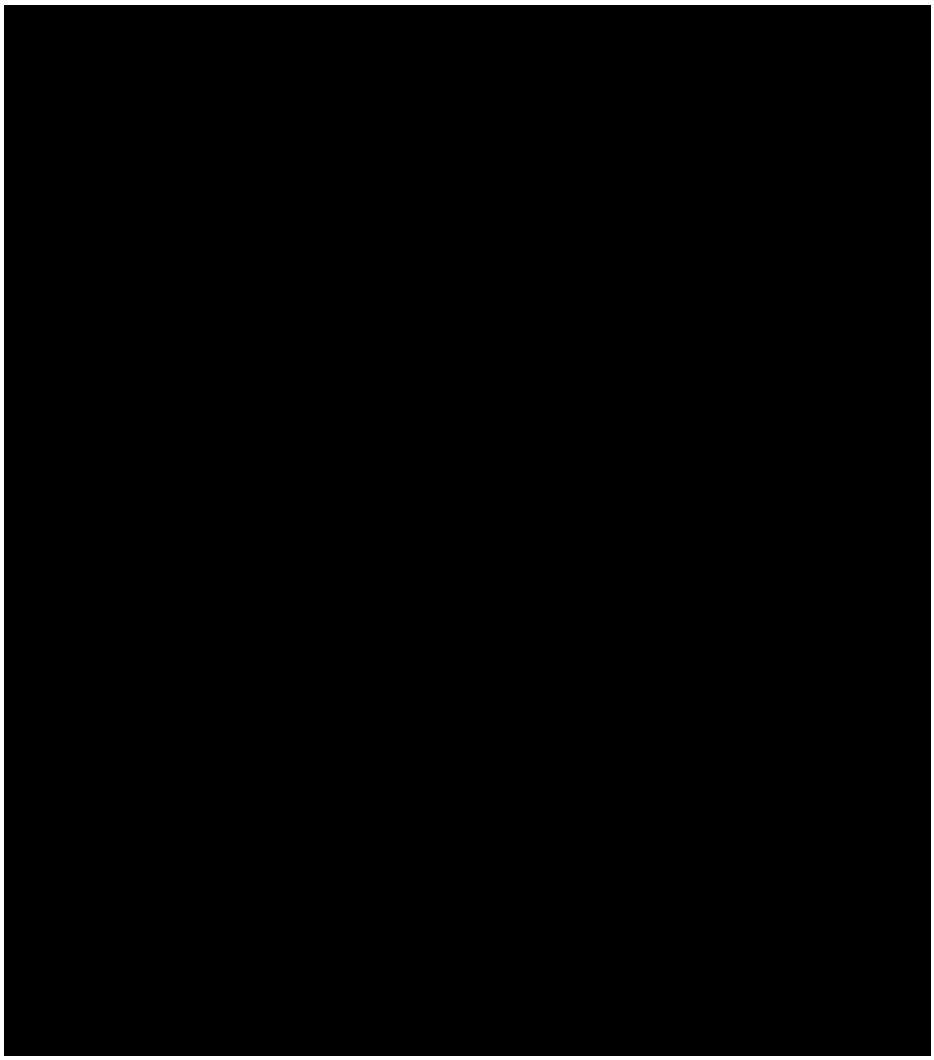
2. FDA US Food and Drug Administration: CITE: 21CFR7.41

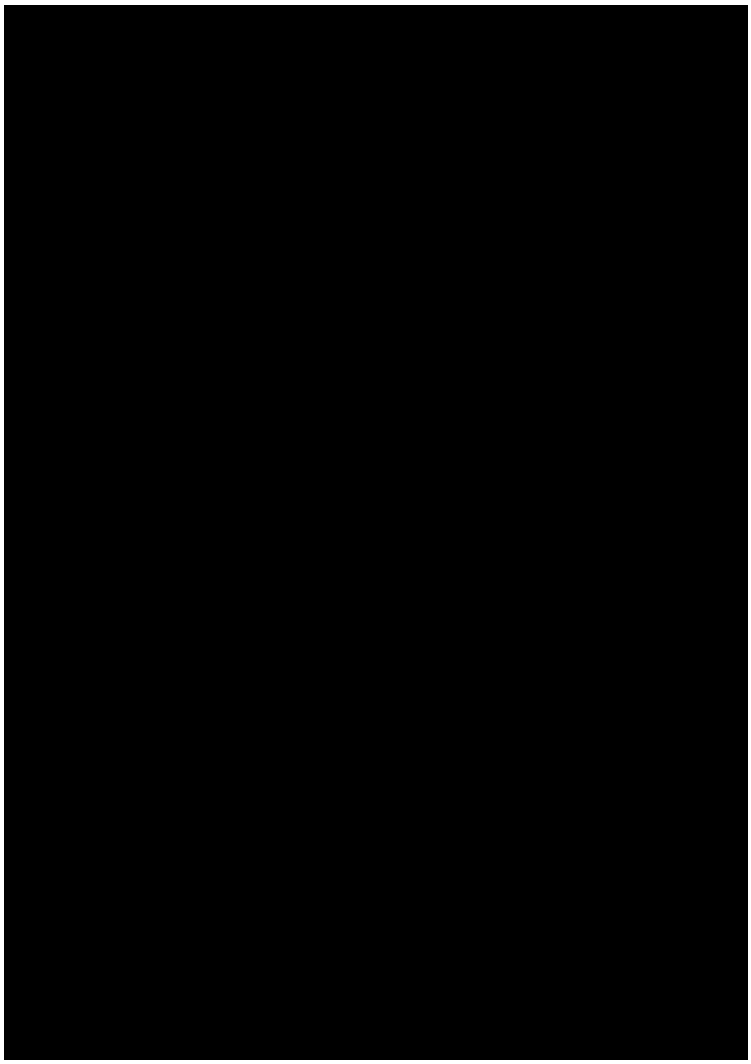












Johnson & Johnson Pacific

DRAFT LETTER TO RETAIL STORES

MEDICAL DEVICE RECALL

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

Date: 21 June 2019

Dear Retailer,

Out of an abundance of caution, Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the voluntary decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a **wholesale and retail level**.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment; consumers can continue to safely use the Spot Treatment as directed.

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

Reason for voluntary wholesale and retail level recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

Our voluntary decision to recall this product at a wholesale and retail level has been taken out of an abundance of caution. Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient. For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury.

The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is safe for use by the general population when used as directed. However, if consumers experience any visual discomfort, they should stop use and consult their healthcare professional.

If consumers have questions or concerns, or if they would like to return the product and the activator, they are encouraged to call our Johnson & Johnson Pacific Consumer Care Centre on 0800 442 582.

If a consumer reports an adverse experience with the product to you directly, please contact our Johnson & Johnson Pacific Consumer Care Centre immediately on 0800 442 582 so that we can investigate fully.

Actions to be taken:

We understand that you have received one or more of the affected devices subject to this voluntary recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Complete the Recall Acknowledgement Form (attached) whether you have stock or not;
- Return the acknowledgement form to your wholesaler;
- Contact your wholesaler to arrange a credit and to organise the return of all affected devices.

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products. If you have any other questions, please don't hesitate to contact the [XXX].

Yours sincerely

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

[redacted]

Johnson & Johnson Pacific

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Johnson & Johnson Pacific

DRAFT LETTER TO WHOLESALERS

MEDICAL DEVICE RECALL

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and Activator

Date: 21 June 2019

Dear [customer name],

Out of an abundance of caution, Johnson & Johnson Pacific Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), has made the voluntary decision to recall the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator at a **wholesale and retail level**.

Affected devices:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask	287825	26202031	3574661329499	357661331874	NA
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202032	3574661329482	3574661332260	3574661332253
Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

Of note, this recall does NOT apply to the NEUTROGENA® Visibly Clear® Light Therapy Acne Spot Treatment; consumers can continue to safely use the Spot Treatment as directed.

Johnson & Johnson Pacific

Reason for voluntary wholesale and retail level recall:

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask on the eye.

Our voluntary decision to recall this product at a wholesale and retail level has been taken out of an abundance of caution. Reports of visual effects associated with use of the NEUTROGENA® Visibly Clear® Light Therapy Acne Mask are rare, generally mild and transient. For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury.

The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is safe for use by the general population when used as directed. However, if consumers experience any visual discomfort, they should stop use and consult their healthcare professional.

If consumers have questions or concerns, or if they would like to return the product and the activator, they are encouraged to call our Johnson & Johnson Pacific Consumer Care Centre on 1800 789 348.

If a consumer reports an adverse experience with the product to you directly, please contact our Johnson & Johnson Pacific Consumer Care Centre immediately on 1800 789 348 so that we can investigate fully.

Actions to be taken:

Our records show that you have received one or more of the affected devices subject to this voluntary recall. We would appreciate your assistance with ensuring this recall can be managed effectively. On receipt of this notice, we ask you to please commence the following actions:

- Complete the **Recall Acknowledgement Form** (attached) whether you have affected medical devices or not and return the form to **dmcharg@its.jnj.com**;
- If the affected medical devices have been forwarded to a retail store, contact that retailer with the attached **Letter to Retailers** and the **Recall Acknowledgement Form**, which they need to fill in and return to you, whether they have affected medical devices or not;
- Before you raise a credit claim, please ensure you have collected all acknowledgement forms and affected devices from your retailers;
- Raise a credit claim in your system and email the claim and the consolidated Acknowledgement Forms to [redacted] at [redacted]**@its.jnj.com;**
- Once the claim has been processed, Johnson & Johnson Pacific Customer Service will contact you to provide your return number and pick up instructions.

Johnson & Johnson Pacific

We apologise for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products. If you have any other questions, please don't hesitate to contact your business manager.

Yours sincerely

[redacted]

Johnson & Johnson Pacific

JOHNSON & JOHNSON PACIFIC PTY LIMITED ABN. 73 001 121 446
45 JONES STREET, ULTIMO NSW 2007, AUSTRALIA. TELEPHONE: 131 565, FACSIMILE: (02) 8260 8109
ADDRESS ALL COMMUNICATIONS TO: LOCKED BAG 5, BROADWAY, NSW 2007

Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

MEDICAL DEVICE RECALL

TGA Recall Reference Number: [Number]

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask

and NEUTROGENA® Visibly Clear® Light Therapy Acne Mask Activator

AFFECTED DEVICES:

NEUTROGENA® Visibly Clear® Light Therapy Acne Mask and NEUTROGENA® Visibly Clear® Light Therapy Activator. The NEUTROGENA® Visibly Clear® Light Therapy Acne Mask is a device intended to treat mild to moderate acne on the face.

Name	ARTG No	SAP Code	APN	TUN	IUN
Neutrogena Visibly Clear Light Therapy Acne Mask	287825	26202031	3574661329499	357661331874	NA
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Neutrogena Visibly Clear Light Therapy Acne Mask Activator	287825	26202034	3574661329482	3574661332260	3574661332253

On behalf of this organisation I acknowledge receipt of the Medical Device Recall notice date [insert date of notice] relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	Batch/Lot/Date	Quantity of stock received	Quantity of unused stock subject to recall (currently in quarantine)
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

☐ Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Name	[redacted]
Position	[redacted]
Organisation	Johnson & Johnson Pacific
Address	45 Jones Street, Ultimo NSW 2007
Email	[redacted]@its.jnj.com
Subject of email	Neutrogena Visibly Clear Light Therapy Acne Mask and Activator [do we need a number?]
Telephone no.	1800 638 047 (press '2')