Australian Government
Department of Health
Therapeutic Goods Administration

The Regulatory Affairs Manager
Edgewell Personal Care Australia Pty Ltd
11 Talavera Road Level 5 Building C
Macquarie Park NSW 2113

Email: ap.others.australia@edgewell.com; s22 [redacted] @edgewell.com

Attention: Regulatory Affairs Officer,

RE:

AUST L	Product Name
206545	Banana Boat Kids Very High Protection Clear Sunscreen Spray SPF 50+
230340	Banana Boat daily PROTECT Very High Protection Clear Sunscreen Spray SPF 50+
265696	Banana Boat SunComfort Very High Protection Clear Sunscreen Spray SPF 50+
287334	Banana Boat Dry Balance Very High Protection Sunscreen Spray SPF 50+
298626	Banana Boat Simply Protect Kids Very High Protection Sunscreen Lotion Spray SPF 50+
298627	Banana Boat Simply Protect Sport Very High Protection Sunscreen Spray SPF 50+
342651	Hawaiian Tropic Silk Hydration Sunscreen Spray SPF 50+ Broad Spectrum
351121	Banana Boat Ultra Very High Protection Clear Sunscreen Spray SPF 50+
355411	Banana Boat Sport Very High Protection Sunscreen Spray SPF 50+
364123	Banana Boat KiDS Very High Protection Sunscreen Spray SPF 50+
366376	Banana Boat Dry Balance Very High Protection Clear Sunscreen Spray SPF 50+
366377	Hawaiian Tropic Silk Hydration Sunscreen Spray SPF 50+

Dear Sir/Madam

Notice under subsection 28(5) of the *Therapeutic Goods Act 1989*

Request for samples of medicine(s)

I refer to the medicine specified above registered on the Australian Register of Therapeutic Goods (ARTG) under the provisions of the *Therapeutic Goods Act 1989* (the Act) and in relation to which Edgewell Personal Care Australia Pty Ltd is listed as the sponsor.

I am a delegate of the Secretary to the Department of Health for the purposes of section 28 of the Act. I am writing to request under subsection 28(5) that you provide samples of medicine specified above to the Therapeutic Goods Administration (TGA) within the period specified in this request.

The samples are requested to enable testing of the quality of the goods, and compliance with legislative requirements applying to listed medicines, in particular the requirements for residual solvents as specified in the ICH guideline Q3C (R8) on impurities: guideline for residual solvents and adopted by the pharmacopoeias. In particular the products will be tested for the presence of the Class 1 solvent benzene.

You will be advised of the outcome of the laboratory testing following completion of the testing. In addition, outcomes of laboratory testing are published biannually in the TGA Database of Laboratory Testing Results http://www.tga.gov.au/ws-labs-index and may also be published in a laboratory report.

Request under subsection 28(5) of the Act

It is a condition of registration under subsection 28(5) of the Act that the person in relation to whom therapeutic goods are registered, if requested by the Secretary or delegate of the Secretary, deliver a reasonable number of samples of the medicine within the period specified and in accordance with any other requirements specified.

In accordance with section 28(5)(h) of the Act, the period specified in any request must include at least 10 working days.

Accordingly, you are requested to provide, to the premises of the TGA by **5:00pm on 14 January 2022**, samples of **the <u>two</u> most recently manufactured batches supplied to the Australian market that have not yet reached their expiry date**, for the products detailed in the table above. Please also provide certificates of analysis for the respective batches in relation to testing for benzene, if available.

Please provide the following:

- Minimum of 4 aerosol containers for each batch

Please note that the TGA office will be closed between midday 24 December 2021 until 4 January 2022 and we will not be able to accept samples during this time.

Please note that it is an offence under subsection 21A(8) of the Act, if a person in relation to whom therapeutic goods are registered does an act or omits to do an act that breaches a condition of the registered of those goods.

For your information, the Act is available at www.legislation.gov.au/Series/C2004A03952.

Review rights

Certain decisions made by the Secretary or a delegate of the Secretary under Part 3-2 of the Act are subject to Ministerial review under section 60. Your rights for reconsideration of this decision to request these samples are set out in **Attachment A.**

Address for Reply

The samples and any response to this notice should be addressed to the following:

s22
Laboratories Branch
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

Contact for further information

If the required sample(s) are unavailable or cannot be submitted within the specified period, or if you require further information or clarification relating to this notice, please contact me by telephone s22, or email at s22 @health.gov.au.

Yours faithfully

Signed and authorised by
s22, A/g Principal Chemist
Delegate of the Secretary
Laboratories Branch

22 December 2021

ATTACHMENT A

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: s22 [redacted] **@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.