



**RE: Update on OCM review - listing notice for sodium fluoride
[SEC=UNCLASSIFIED]**

Catherine Oh to: LayKhoon.Choo [REDACTED]
Cc: "Jennifer.Burnett [REDACTED], Dusanka Sabic [REDACTED], Bronwyn Capanna

15/11/2013 11:02 AM

Thanks you very much for the amendment and for the notice!
Regards,
Catherine

From: LayKhoon.Choo [REDACTED] [mailto:LayKhoon.Choo [REDACTED]]
Sent: Friday, 15 November 2013 10:54 AM
To: Catherine Oh
Cc: Jennifer.Burnett [REDACTED]
Subject: RE: Update on OCM review - listing notice for sodium fluoride [SEC=UNCLASSIFIED]

Dear Ms Oh

I would like to inform you that the TGA has finalised the review for sodium fluoride and this substance is now permitted for use as an active ingredient in listed medicines with the conditions of listing as stated in the box below. Please refer to Listing Notice 2013 (No. 6) [<http://www.comlaw.gov.au/Details/F2013L01925>], noting that the earlier Listing Notice for sodium fluoride - Listing Notice 2008 (No. 1) has been revoked.

preparations, for the purpose of Item 3 of Part 1 of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations), that contain 'sodium fluoride' as a therapeutically active ingredient, subject to the following conditions:

- the preparations are for dental use only; and
- 'sodium fluoride' is for use only in pastes, powders or gels for dental hygiene; and
- 'sodium fluoride' is in combination with at least one of the therapeutically active ingredients referred to in item 3, Part 1 of Schedule 4 to the Regulations; and
- the concentration of fluoride ion is not more than 1,500 mg/kg; and
- when the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation complies with the requirements of the *Required Advisory Statements for Medicine Labels* ; and
- any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

Kind regards

Lay Khoon

From: Catherine Oh <[REDACTED]>
To: "Jennifer.Burnett [REDACTED]" <Jennifer.Burnett [REDACTED]>
Cc: "Trisha.Garrett [REDACTED]" <Trisha.Garrett [REDACTED]>, "Peter.Bird [REDACTED]" <Peter.Bird [REDACTED]>
Date: 13/06/2013 03:24 PM
Subject: RE: Update on OCM review - listing notice for sodium fluoride [SEC=UNCLASSIFIED]

Thank you Jenny!
Regards,
Catherine

From: Jennifer.Burnett [REDACTED] [mailto:Jennifer.Burnett [REDACTED]]
Sent: Thursday, 13 June 2013 1:55 PM
To: Catherine Oh
Cc: Trisha.Garrett [REDACTED]; Peter.Bird [REDACTED]
Subject: Update on OCM review - listing notice for sodium fluoride [SEC=UNCLASSIFIED]

Dear Ms Oh,

Further to the TGA email of 22 April 2013 (sent by Trisha Garrett, Head OCM), I can now inform you that review of the availability of sodium fluoride as an active ingredient in listed medicines has been completed.

The TGA has determined that the current availability of this ingredient should be changed to provide consistency with the current scheduling of the substance in the *Standard for the Uniform Scheduling of Medicines and Poisons Number 3*. To enable this to occur, a new listing notice will be drafted and the existing notice revoked. This process should be completed within the original 60 day period proposed in our earlier email, but I will inform you if any delays are experienced.

Please contact me if you have any questions in the meantime.

regards,
Jenny

Jenny Burnett
Director
Pre-market Assessment Section
Office of Complementary Medicines

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