RE: Response to Accord query regarding listing notice - Fluoride [SEC=UNCLASSIFIED]

Catherine Oh to: Trisha.Garrett[redacted] 22/04/2013 04:07 PM
Cc: "Peter.Bird[redacted] "Jennifer.Burnett[redacted]
Bronwyn Capanna , Dusanka Sabic

Dear Trisha

Thank you very much for your response. I look forward to the Delegate's decision. Meanwhile, please feel free to contact me if you require any further information.

Regards,
Catherine

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From: Trisha.Garrett[redacted] [mailto:Trisha.Garrett[redacted]
Sent: Monday, 22 April 2013 4:03 PM
To: Catherine Oh
Cc: Peter.Bird[redacted] Jennifer.Burnett[redacted]
Subject: Response to Accord query regarding listing notice - Fluoride [SEC=UNCLASSIFIED]

Dear Ms Oh,

Thank you for providing information regarding the use of sodium fluoride as an active ingredient in listed medicines and the apparent anomaly with its availability for use in cosmetics.

As you are aware, this active ingredient is permitted for use by way of a listing notice that is published on the Federal Register of Legislative Instruments. This listing notice permits use of sodium fluoride under certain conditions and these conditions would have been developed in response to safety and/or quality issues that were identified at the time of publication of the listing notice. I agree that it appears that certain safety concerns may now have been resolved and consequently the conditions may need to be reviewed.

Evaluation of relevant quality and safety data, and preparation of listing notices, for new ingredients for use in listed medicines is usually conducted within the Office of Complementary Medicines (OCM). This evaluation is undertaken to determine whether a substance is of sufficiently low risk to allow its inclusion in listed medicines and to characterise the precise nature of the substance. The outcome of the evaluation is then considered by the delegate before a decision is made under section 9A(5) of the *Therapeutic Goods Act 1989* to publish a listing notice.

In this instance, you are seeking review of an existing ingredient that may result in the need for a new listing notice and this request will be handled by the OCM in a manner consistent with that for evaluation of new ingredients. However, the change that you seek appears to rely on the change to the scheduling of sodium fluoride in the Standard for the Uniform Scheduling for Medicines and Poisons. I therefore do not believe that, at this time, you need to submit further supporting data nor any fees that may be associated with requests to the TGA for safety reviews of ingredients.

The TGA will commence a review of this ingredient, comprising a review of all current conditions placed on its use, the scheduling requirements for this substance and any other relevant information to ensure that no other additional issues need to be considered prior to drafting a new listing notice. That is, if the delegate agrees that a change to the limit on fluoride in listed medicines can be increased to 1500 mg/kg, the existing listing notice will be revoked and replaced with a new notice.

I would estimate that this process will take approximately 60 days and we will inform you if any further information is required during this time or if there are any significant changes to the proposed time frame. You will also be notified of the delegate's decision at the conclusion of the process.

As you may be aware the arrangements for ingredients permitted for use in listed medicines are to change with the implementation of legislation for permitted ingredients (Section 26BB of the *Therapeutic Goods Act 1989*). There will be associated changes to processes such as this one accordingly.

If you have any further queries regarding this process, please contact Jenny Burnett, Director, PREMAS, OCM on 02 6232 8280.

Regards

Trisha

Trisha Garrett
Head
Office of Complementary Medicines

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