For advice and draft response: TGA/Accord bilateral discussion - Fluoride [SEC=UNCLASSIFIED]

Trisha Garrett to: Jennifer Burnett 19/04/2013 08:06 AM

History: This message has been replied to.

Jenny
Thanks for this.
I would like to discuss, but in the meantime, could you draft a response which states that OCM are responsible for listing notices, we will be in contact shortly to
discuss any information we may require,
provide an overview of the process and
anticipated time frames.
I would like to respond today so could I have the draft by 3pm please.
Thank you
Trish

Trisha Garrett
Head
Office of Complementary Medicines

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[redacted] TGA Health Safety Regulation

Jennifer Burnett Trish, I have had a brief look at this request... 15/04/2013 05:55:29 PM

From: Jennifer Burnett/TGA/Health
To: Trisha Garrett/TGA/Health[redacted]
Date: 15/04/2013 05:55 PM
Subject: Re: For advice and draft response: TGA/Accord bilateral discussion - Fluoride [SEC=UNCLASSIFIED]

Trish,

I have had a brief look at this request and provide you with the following comments

- conditions placed on the use of permitted ingredients relate to ensuring that the substance is of appropriate quality and safety to be used as an ingredient. In this instance I would assume that the limit on F is a result of safety issues
- if the assumption above is correct, revision of this limit would require submission of new safety data. In this instance, one could argue that the scheduling entry constitutes assurance of safety and no further data are necessary. However, we need to look at the entire scheduling requirements for this substance to ensure that no other potential issues need to be considered as well.
- as the conditions are written into the listing notice, and not included in sch 4 to the Regulations, the existing notice would need to be revoked and a new listing notice included on the FRLI. I am not sure how this would work - whether it would need to be considered a new ingredient? whether we can draft a new notice that would be taken to replace the existing? ... If its not a new ingredient, there is no mechanism in the legislation for evaluation of an existing ingredient (our problems with r16GA),

although there is an entry in sch 9 to the Regulations that specifies a fee for a safety review (noting that there seems to be little need for one in this instance). Common sense would suggest that in this instance, it would not be considered a new ingredient, so I would need to speak to OLS re mechanisms (Peter Bird may be more familiar with this than I).

My feeling is that the TGA could consider the email below as a formal request for review of current conditions placed on a permitted ingredient and that no further data are required at this time, however I am not sure of the priority that we could give this 'evaluation' given that we have others on hand for which stakeholders have paid fees.

In addition, we perhaps need to be careful that it doesn't set a precedent for the review of conditions of any ingredient, as in many instances a substantial evaluation process would have to be undertaken (the need for which, I presume, is recognised by the existence of the safety evaluation fee).

Please let me know if this information is of assistance and whether any further information is needed. I do have to report again tomorrow for jury selection, but will try and keep an eye on things as I did last week if I am out of the office for an extended period.

Jenny

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

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[redacted]

Trisha Garrett Hi Jenny another query for advice and draft... 14/04/2013 10:56:49 AM

From: Trisha Garrett/TGA/Health
To: Jennifer Burnett/TGA/Health[redacted]
Date: 14/04/2013 10:56 AM
Subject: For advice and draft response: TGA/Accord bilateral discussion - Fluoride [SEC=UNCLASSIFIED]

Hi Jenny

another query for advice and draft response pls.
I would appreciate advice by Tuesday so that I can advise Peter.
Trish

Trisha Garrett
Head
Office of Complementary Medicines

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[redacted] TGA Health Safety Regulation

----- Forwarded by Trisha Garrett/TGA/Health on 14/04/2013 10:54 AM -----

From: Peter Bird/TGA/Health
To: Trisha Garrett/TGA/Health[redacted]
Date: 12/04/2013 04:30 PM
Subject: Fw: TGA/Accord bilateral discussion - Fluoride [SEC=UNCLASSIFIED]

Hi Trisha,
I am not sure of the process for listing notices and whether this happens in OCM - please can you advise me about this request.
Thanks,
Pete

Dr Peter Bird
A/g Head of Office
Office of Medicines Authorisation
Therapeutic Goods Administration
Tel: (02) 62328100
----- Forwarded by Peter Bird/TGA/Health on 12/04/2013 04:28 PM -----

From: Catherine Oh
Sent: Monday, 25 February 2013 12:11 PM
To: 'peter.bird[redacted]
Cc: Bronwyn Capanna; Dusanka Sabic
Subject: TGA/Accord bilateral discussion - Fluoride

Hi Peter

As discussed at the TGA/Accord bilateral meeting, below is the detail of the discrepancy in the fluoride in toothpaste.

As you are aware, the acceptable level of fluoride in toothpaste has been extensively debated by the National Drugs and Poisons Schedule Committee (NDPSC) and changes made to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) in 2008 to allow toothpastes containing up to 1500mg/kg fluoride for both therapeutic and non-therapeutic use to be exempted from scheduling requirements. The wording of the Schedule 3 entry for fluoride is below:

FLUORIDES for human topical use:

(a) in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure **except** when included in or expressly excluded from Schedule 2; or

(b) in non-liquid preparations containing 5500 mg/kg or less of fluoride ion **except**:

(i) in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the requirements of the *Required Advisory Statements for Medicine Labels* ;

(ii) in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect:

(A) Do not swallow; and

(B) Do not use [this product/name of product] in children six years of age or less; or

(iii) in preparations for supply to registered dental professionals or by approval of an appropriate authority.

Unfortunately the Listing Notice for fluoride was not updated when this change was made to the SUSDP. The listing notice (gazetted earlier in 2008) only allows up to 1000mg/kg fluoride in listed medicines (http://www.comlaw.gov.au/Details/F2008L00384). As toothpastes that are sold as cosmetics are allowed to contain up to 1500mg/kg of fluoride, the restriction on toothpastes that are listed medicines appears to be an anomaly.

We would like to see this corrected, and would appreciate your advice on next steps.

Kind regards,
Catherine

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