




John Hall

17/05/2005 02:26 PM

To: Greg Purcell/TGA/Health@Health_gov_au
cc: libby.kerr@health.gov.au
Subject: Re: Drafting of Gazette Notice for Sodium Monofluorophosphate (SMPF) 

Greg

Thanks for this - I would prefer "(b) claims in relation to the fluoride content"

For the purposes of the Minutes to Mr Slater and Mr Pyne, can you please provide the actual drafting of the replacement version of the Excluded Goods Order (EGO) because I think this level of detail is needed in the Minutes.

- Who will do this?
- How long will it take? My concern over the timing stems from the concern that the fluoride sponsor is awaiting gazettal and it sounds like that could be along way off because of the necessary accompanying changes to the EGO.

Thanks

jh

Greg Purcell

Greg Purcell

17/05/2005 01:51 PM

To: John Hall/TGA/Health@Health_gov_au, Libby Kerr/TGA/Health@Health_gov_au
cc: Terry Lee/TGA/Health@Health_gov_au, Pio Cesarin/TGA/Health@Health_gov_au
Subject: Re: Drafting of Gazette Notice for Sodium Monofluorophosphate (SMPF)

John/Libby,

I refer to our meeting yesterday in relation to this matter.

I confirm that the proposed wording of the revised draft gazettal listing notice under section 9A(5) of the *Therapeutic Goods Act 1989* (the Act) set out in Libby's email below is acceptable and I do not propose any change to it.

However, as discussed gazettal of the listing notice by itself may not be sufficient to ensure that the preparations in question are required to be listed in the Australian Register of Therapeutic Goods (the ARTG). There is a risk that the current *Therapeutic Goods (Excluded Goods) Order No. 1 of 2004*, dated 31 August 2004, may, unless amended, have the effect of excluding the relevant preparations from being therapeutic goods so that they would not have to be included in the ARTG despite the listing notice.

To remove this risk it is suggested that a new Excluded Goods Order be made prior to, or at the same time, as the listing notice is made. It is suggested that the new Order would substantially replicate the current Order with the following amendments:

- column 2 of Item 2 in the Table in paragraph 3 be reworded as follows:
"Oral hygiene preparations or devices (including dentifrices, mouth washes, breath fresheners, brushes and flosses) other than those:
(a) included in a Schedule to the Poisons Standard; or
(b) required to be included in the Australian Register of Therapeutic Goods."
- a replacement Revocation clause revoking the current Order.