

John Hall

25/05/2005 12:30 PM

To: Paul Archer/TGA/Health@Health_gov_au

cc: libby.kerr@health.gov.au, Andrea

Hinschen/TGA/Health@Health_gov_au, Greg

Purcell/TGA/Health@Health_gov_au

Subject: Excluded Goods Order Sodium Monofluorophosphate (SMFP)

Paul

Further to my earlier email of 10 May 2005, letting you know of our planned gazettal of SMFP (amendments to the Regs), I am now advised by Legal Unit that, for clarity, the Excluded Goods Order also needs amendment to 'unexclude' what will now become allowable therapeutic goods provided certain conditions are met.

The proposed amendment to the Order will read

Oral hygiene preparations or devices
(including dentifrices, mouth washes,
breath fresheners, brushes and flosses)
~~that are not~~ 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.

The intent is to

1. exclude normal toothpastes; but
2. still require Registered OTC [fluoride+Registerable active] toothpastes and our new Listed [fluoride+Listed active] toothpastes to be on the ARTG.

[Note the wording "required to be in the ARTG" refers to Listed meds which "must" be included in the ARTG.]

Can you again please run your eye over it to see we have no unintended consequences on your products. Should I also ask DSEB the same question?

Thanks

jh

— Forwarded by John Hall/TGA/Health on 25/05/2005 12:08 PM —

Libby Kerr

25/05/2005 11:54 AM

To: John Hall/TGA/Health@Health_gov_au

cc:

Subject: Excluded Goods Order



Excluded Goods Order No 1 2005 - May 05.doc