



## MINUTE TO THE MINISTER/PARLIAMENTARY SECRETARY

PARLIAMENTARY SECRETARY MCLUCAS

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### APPROVAL OF NEW INGREDIENTS FOR USE IN LISTED MEDICINES

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#### PURPOSE:

To advise you of the approval of [REDACTED] Sodium fluoride for use as active ingredients in Listed medicines.

#### ISSUE

2. The National Manager of the Therapeutic Goods Administration has signed Listing Notices approving these substance for use in Listed medicines.

#### BACKGROUND

3. In general, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia. Medicines may be Listed or Registered depending on the associated level of risk. Registered products are subject to full evaluation of quality, safety and efficacy prior to market approval. Listed medicines are subjected to a lower level of regulation in line with their low risk. Listed medicines may only contain ingredients that are pre-approved for this purpose.

4. Following evaluation of its quality and safety, a therapeutic goods ingredient is approved for use in Listed medicines via a legislative instrument called a Listing Notice. *Therapeutic Goods (Listing) Notice 2007 (No. 3)* and *Therapeutic Goods (Listing) Notice 2007 (No. 4)* (the Listing Notices) are legislative instrument made under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act). The Listing Notices allow medicines containing [REDACTED] and Sodium fluoride to be included in the part of the ARTG for Listed medicines, consistent with the low risk presented by these ingredients.

[REDACTED]

6. Sodium fluoride is a source of fluoride that is widely used in toothpastes at concentrations of fluoride ion of up to 1,000 mg/kg without evidence of safety concerns. A review by the TGA did not reveal any safety concerns with sodium fluoride that would preclude its use in Listed medicines provided that:

- the concentration of the fluoride ion is not more than 1,000 mg/kg;
- the substance is for use only in pastes, powders or gels for dental hygiene; and
- claims in relation to fluoride content are restricted to those relating to improvements in oral hygiene or the use of fluoride for the prevention of tooth decay.

7. Subsection 9A(5) of the Act allows the Minister for Health and Ageing to publish a notice in the *Commonwealth of Australia Gazette*, requiring certain goods to be in the part of the Australian Register of Therapeutic Goods for listed goods. This mechanism facilitates the approval of new listable

substances. The Parliamentary Secretary to the Minister for Health and Ageing delegated authority, under Section 9A(5) of the Act, to the National Manager of the TGA.

8. Pursuant to subsection 9A(6) of the Act, when Schedule 4 of the Regulations is amended to include reference to a substance that has been the subject of Listing Notice, the Listing Notice ceases to have effect.

**Consultations:**

**COMMUNITY AWARENESS**

10. There are no community awareness opportunities relating to this item.

**RECOMMENDATION**

**R2.** That you NOTE that Sodium fluoride has been approved for use as an active ingredient in Listed therapeutic goods for oral use with certain conditions.

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Dr Rohan Hammett  
National Manager  
Therapeutic Goods Administration  
Outcome: 1: Population Health  
February 2008

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**JAN MCLUCAS**

**R2. NOTED**

Contact Officer: Dr David Briggs (02) 6232 8439  
TGA/Office of Complementary Medicines

MINISTER’S COMMENTS:

Advice Rating	1	2	3	4	5	Comments
Timeliness						
Presentation						
Quality of advice						

Poor

Satisfactory

Excellent

ATTACHMENTS: