



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

R10/397125

Minute

National Manager
TGA

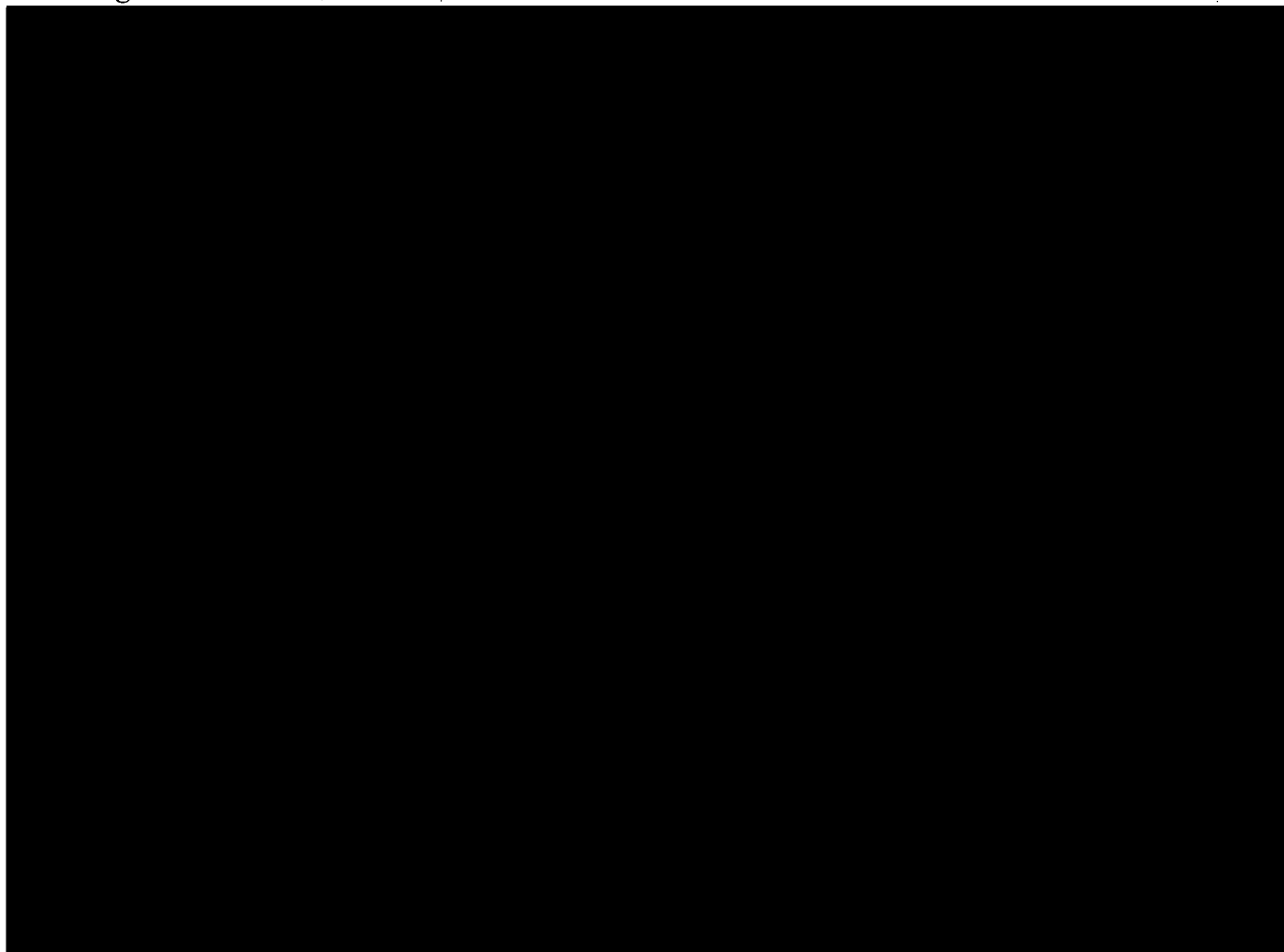
NEW COMPLEMENTARY MEDICINE SUBSTANCES FOR USE IN LISTABLE GOODS

Purpose

To seek your agreement for the approval of two new substances for use in Listed medicines:

- [REDACTED]
- Sodium fluoride for use in toothpaste products, subject to certain conditions

Background



Sodium fluoride

Sodium fluoride is the subject of monograph of the *British Pharmacopoeia* and its safety profile is well established in this application.

Sodium fluoride is a source of fluoride that is widely used in toothpaste products at concentrations of fluoride ion of up to 1,000 mg/kg without evidence of safety concerns. A safety review by the Non-Prescription Medicines Branch did not reveal any safety concerns with this source of fluoride that would preclude the use of this substance 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 the cleaning of teeth; 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.

"Fluorides" are listed in schedules 2, 3 and 4 of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). However, the SUSDP excludes from scheduling fluorides in dental hygiene, whitening or bleaching products that are pastes, powders or gels for use on teeth, containing 1 000 mg/kg or less of fluoride ion. Products for different purposes, in different forms, or with a higher concentration of fluoride ion are not excluded from scheduling and would therefore be ineligible for Listing on the Australian Register of Therapeutic Goods.

The Regulatory Practice Committee (RPC) of the TGA was notified of this listing at its meeting of 13 November 2007.

Regulatory basis for this request

Subsection 9A(5) of the Act authorises 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 prior to the inclusion of these substances in the schedule of the Therapeutic Goods Regulations 1990 that sets out therapeutic goods that are to be included in the part of the Australian Register of Therapeutic Goods for Listed goods.

Pursuant to the commencement of the *Legislative Instruments Act 2003* on 1 January 2005, effect is given to these notices through registration on the Federal Register of Legislative Instruments (FRLI), rather than gazettal.

The Parliamentary Secretary to the Minister for Health and Ageing delegated authority, under subsection 9A(5) of the Act, to the National Manager of the TGA. Subsection 9A(5) notices allowing the use of [REDACTED] and Sodium fluoride as active ingredients in Listed medicines are attached for your signature.

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.

A Minute advising Senator McLucas of the new listable substances has been prepared and is attached for your signature.

These documents have been presented to Legal Services Branch for checking, and their comments have been incorporated.

RECOMMENDATION

R1 That you SIGN the two attached Listing Notices (to be returned to the TGA Legal Unit for registration on FRLI).

R2 That you SIGN the attached Minute to the Parliamentary Secretary.

Dr David Briggs
Director
Office of Complementary Medicines
January 2008

Attached for signature:

- 1) Listing Notice for registration on the Federal Register of Legislative Instruments.
 - a) [REDACTED]
 - b) Sodium fluoride
- 2) Explanatory Statements to accompany Listing notices
 - a) [REDACTED]
 - b) Sodium fluoride
- 3) Minute to the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan Lucas.