***Therapeutic Goods Act 1989***

**Therapeutic Goods (Listing) Notice 2013 (No. 6)**

I, JOHN SKERRITT, National Manager of the Therapeutic Goods Administration, delegate of the Minister for Health for the purposes of subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act) and acting under that provision, HEREBY:

1. REVOKE Therapeutic Goods Listing Notice 2008 (No.1); and
2. Require the following therapeutic goods to be included in the part of the Australian Register of Therapeutic Goods (the Register) for listed goods:

* preparations, for the purpose of Item 3 of Part 1 of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations), that contain ‘sodium fluoride’ as a therapeutically active ingredient, subject to the following conditions:
* the preparations are for dental use only; and
* ‘sodium fluoride’ is for use only in pastes, powders or gels for dental hygiene; and
* ‘sodium fluoride’ is in combination with at least one of the therapeutically active ingredients referred to in item 3, Part 1 of Schedule 4 to the Regulations; and
* the concentration of fluoride ion is not more than 1,500 mg/kg; and
* when the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation complies with the requirements of the *Required Advisory Statements for Medicine Labels*; and
* any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

This Notice commences from the day after it is registered on the Federal Register of Legislative Instruments.

Pursuant to subsection 9A(6) of the Act, this Notice ceases to have effect on the day that amendments to the Regulations come into effect to require inclusion of the therapeutic goods listed in this Notice in the part of the Register for listed goods.

Dated this 1st day of November 2013

(Signed by)

John Skerritt

Delegate of the Minister for Health