Australian Government

Department of Health
Therapeutic Goods Administration

Instrument of Approval under the *Therapeutic Goods Act 1989*

Approved form for providing information in relation to applications under section 23 of the *Therapeutic Goods Act 1989* for the registration of over-the-counter medicines

I, Lyndall Soper, Assistant Secretary, Complementary and OTC Medicines Branch, a delegate of the Secretary of the Department of Health for the purposes of section 23 of the *Therapeutic Goods Act 1989* (the Act):

REVOKE the approval made by Terry Slater under subsection 23(2) of the Act dated 23 June 2003, as to the information that must be provided in relation to an application for the registration of an OTC medicine, being a therapeutic good of the kind mentioned in Part 3 of Schedule 10 to the *Therapeutic Goods Regulations 1990* (the Regulations); and

in relation to an application for the registration of a therapeutic good of the kind mentioned in Part 3 of Schedule 10 to the Regulations, to which the instrument "Approved manner of making an application under section 23 of the Therapeutic Goods Act 1989 for a registered OTC medicine" dated 1 February 2016 applies,

APPROVE, for the purposes of paragraph 23(2)(b) of the Act, the following information to be provided in the form set out below:

(a) information contained in an application dossier, and submitted electronically, that meets the requirements specified in the following documents or material on the website of the Therapeutic Goods Administration, for the relevant application level and type:

(i) *General dossier requirements* dated 24 July 2015; and

(ii) *Common Technical Document Module 1: OTC medicines* dated 1 March 2016 and described as Version 1.1; and

(iii) *Mandatory requirements for an effective over-the-counter medicines application* dated 1 March 2016 and described as Version 1.1.

Lyndall Soper
Delegate of the Secretary
March 2016