



Therapeutic Goods (Provisional Determinations and Orphan Drug Designations—Extension) Approval of Application Form

I, Adrian Bootes, Assistant Secretary, Prescription Medicines Authorisation Branch, a delegate of the Secretary of the Department of Health for the purposes of section 22E of the *Therapeutic Goods Act 1989* and regulation 16L of the *Therapeutic Goods Regulations 1990*, make the following instrument.

Dated 4th April 2018

A handwritten signature in blue ink, appearing to read 'A. Bootes', is written over a horizontal line.

ADRIAN BOOTES

Delegate of the Secretary of the Department of Health

1 Name

This instrument is the *Therapeutic Goods (Provisional Determinations and Orphan Drug Designations—Extension) Approval of Application Form*.

2 Definitions

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

initial period has the meaning given by subsection 22E(2) of the Act.

orphan drug designation means a designation under regulation 16J of the Regulations.

provisional determination means a determination under section 22D of the Act.

Regulations means the *Therapeutic Goods Regulations 1990*.

TGA means the part of the Department of Health known as the Therapeutic Goods Administration.

3 Applications to which this instrument applies

This instrument applies to the following applications:

- (a) an application under subsection 22E(3) of the Act for an extension of the initial period of a provisional determination;
- (b) an application under regulation 16L of the Regulations for an extension of an orphan drug designation.

4 Approved form

The approved form for an application to which this instrument applies is the online form titled *Prescription Medicines – Designation/Determination Extension Application* in the TGA's electronic lodgement facility, completed in accordance with the relevant instructions in that form.

Note: The TGA's electronic lodgement facility is on the TGA Business Services website (<http://www.tga.gov.au/tga-business-services>).