

HISTORICAL DOCUMENT



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

Draft Therapeutic Goods Order No. <to be allocated>
Standard for human albumin

I,, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* ('the Act') and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the Act, HEREBY:

1. DETERMINE that matters specified in this Order constitute a standard for albumin from humans:
 - a. for therapeutic use; or
 - b. for use as an ingredient or component in the manufacture of a therapeutic good (other than a medical device),
other than for:
 - c. an export only medicine; or
 - d. a personal import as described under Item 1 of Schedule 5 of the Regulations.

Standard

Albumin from humans must comply with the monograph for albumin in the British Pharmacopoeia or the European Pharmacopoeia.

Definitions

In this Order:

monograph means the requirements of, and definitions within, an individual or general monograph of the British Pharmacopoeia or the European Pharmacopoeia, read in conjunction with the General Notices contained in the same edition that are applicable to that monograph.

Commencement

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

Dated thisday of2009

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Delegate of the Minister for Health and Ageing