Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under Subsections 19A(1), (6) and (7)

Instrument of Approval for the Importation and Supply of Unregistered Product(s) in Australia

Pursuant to my powers under subsections 19A(1), (6) and (7) of the *Therapeutic Goods Act 1989* I, DAVID GRAHAM, Acting National Manager of the Therapeutic Goods Administration of the Commonwealth Department of Health and Ageing, HEREBY GRANT approval to those person(s) identified in column 1 of Schedule 1 to this approval, to import and supply in Australia, the unapproved therapeutic good(s) detailed in the corresponding columns 2 and 3 of Schedule 1. Subject to Clause 2 below, this approval is to operate from May 1st 2006 until May 31st 2007.

This approval is subject to the following conditions:

1. This approval is solely for the product(s) specified in Schedule 1 (which includes the source of the goods), and for the indication(s) outlined in column 2 of Schedule 1; and

2. This approval lapses if:

   (a) either:

      (i) the period specified above lapses; or
      (ii) a decision is made under section 25 of the *Therapeutic Goods Act 1989* (the Act) in relation to the good(s);

      whichever should occur first; or

   (b) I am satisfied that:

      (i) paragraph 19A(1)(a), (b), (c) or (d) of the Act, as the case requires, no longer applies in relation to the good(s); or
      (ii) a condition of this approval has been contravened; and

      I have given to the person(s) to whom this approval is granted a notice to that effect; and

3. The goods shall be sourced from manufacturing plants with acceptable evidence of Good Manufacturing Practice (GMP); and

4. The goods shall be supplied with labelling and prescribing information that is in English and that has been approved by the Director, Drug Safety and Evaluation Branch of the Therapeutic Goods Administration within the Department of Health and Ageing.

Dated this eleventh day of April 2006

DAVID GRAHAM
NATIONAL MANAGER
Therapeutic Goods Administration
Department of Health and Ageing

Schedule 1: Therapeutic goods approved for importation and supply under subsection 19A(1), (6) and (7) of the *Therapeutic Goods Act 1989*.

	Column 1	Column 2	Column 3
	Person granted approval	**Therapeutic Goods**	**Country of Origin and manufacturer**
1.	[redacted] Aspen Pharmacare Australia Pty. Ltd. ABN 51 096 236 985 Suite 1, 1st Floor 34-36 Chandos St. St. Leonards NSW 2065	PAN BENZATHINE PENICILLINE FOR INJECTION, 1,200,000 I.U. vials.	France Manufactured by: Panpharma Z1 du Clairay Luitre Fougeres 35133 France (TGA manufacturer client ID 46899)