Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY A FORM SPECIAL ACCESS SCHEME

READ CAREFULLY BEFORE COMPLETING

This completed document constitutes the legal authority for an Australian sponsor to supply the specified product and should be forwarded to the Australian Sponsor of the product, accompanied by a prescription where necessary.

A copy of the form must be forwarded to the TGA within 28 days of its completion.
Send to: Medical Officer - SAS, TGA, PO BOX 100, WODEN ACT 2606 [Fax No: (02) 6232 8112 for medicines; and (02) 6232 8785 for medical devices]

The basis for these SAS arrangements is that responsibility for prescribing an unapproved therapeutic good appropriately rests with the patient's medical practitioner and the patient. Category A patients are defined in the legislation as "persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment". Under s31A(2) and 41JD of the *Therapeutic Goods Act 1989* (the Act) the TGA may seek clarification of the Category A classification of patients. In addition, under s61(3A) of the Act the TGA may release details of inappropriate supply and/or use of unapproved medicines and medical devices to State and Territory authorities. **If you intend to import this product, be aware that an import permit may be required for Customs purposes. Details of goods for which a permit is required may be found at www.tga.gov.au**.

PATIENT AND PRODUCT DETAILS - COMPLETE ALL <u>RELEVANT</u> SECTIONS AND <u>PRINT CLEARLY</u>

PATIENT DETAILS: (initials/age or DOB, sex)

DIAGNOSIS:

MEDICINE/DEVICE:

DOSAGE/PRODUCT FORM: STRENGTH:

ROUTE/METHOD OF ADMINISTRAT^{N}: DOSAGE:

DURATION OF TREATMENT:

QUANTITY TO BE SUPPLIED:

AUSTRALIAN SPONSOR OF PRODUCT:

NAME AND ADDRESS FOR SUPPLY OF PRODUCT (HOSPITAL, PHARMACIST OR DOCTOR):

MEDICAL PRACTITIONER CERTIFICATION - COMPLETE ALL SECTIONS AND <u>PRINT CLEARLY</u>

I, the undersigned, a registered medical practitioner in a State/Territory of Australia, certify that:

- In my opinion the patient above is a Category A patient as defined in regulation 12A of the *Therapeutic Goods Regulations 1990* /regulation 7.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (delete as appropriate)
- I am prepared to prescribe the medicine/medical device requested; and
- I have obtained the informed consent of the patient, or the patient's legal representative, to the proposed treatment.

NAME: SIGNATURE:

PHONE: DATE / /

ADDRESS: