Fax to: 02 6232 8112 – Medical officer, SAS.

EDS-8.7

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TGA THERAPEUTIC GOODS ADMINISTRATION

CATEGORY B FORM
SPECIAL ACCESS SCHEME

Health and Aged Care

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient details (initials, ID or URN, DOB, Sex): [redacted]

Diagnosis: RHEUMATOID ARTHRITIS (VARIANT) Previous SAS No.: N.A.

Clinical justification for use of product *Include appraisal of seriousness of patient's condition; detail previous treatments and expected benefits from use of the product*: SEVERE, PROGRESSIVE SYNOVITIS, UNCONTROLLED USING CONVENTIONAL THERAPIES INCLUDING DISEASE MODIFYING DRUGS. NOTE: PATIENT DECLINES ETANERCEPT + INFLIXIMAB.

Product details *Attach efficacy and safety data to support proposed use of the product and details of intended monitoring regime. *Complete for medicines only.*

Active* ingredient: ADALIMUMAB (D2E7) Trade name /Device name:

Company/supplier: ABBOTT

Dose form*: 40mg Route of administration*: SUBCUTANEOUS.

Dosage*: 40mg S.C. FORTNIGHTLY Duration of treatment: INDEFINATE.

Prescribing doctor details

Name: [redacted] Hospital: [redacted]

Postal address: [redacted] Department: [redacted]

Phone: [redacted]

Fax number: [redacted]

Signature: [redacted] 7/7/02

Approved [redacted] 11/7/02

Form no. 2950 (0103)

new file requested 19.7

TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241

Commonwealth Department of Health and Ageing

[redacted]

Dear [redacted]

Re: Adalimumab

I refer to your request received 8 July 2002 concerning approval to supply **Adalimumab** for use in the treatment of one of your patients.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of **Adalimumab** for use in the treatment of your patient [redacted]

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this drug product in the proposed usage.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, in the case of a major company, there may be implications for the company's indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

Permission is given subject to the following:

1. The approval is given for the supply of up to six (6) months' therapy of the above drug at a dosage as per manufacturer's instructions.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until **Adalimumab** is marketed in Australia, whichever is sooner.

3. The approval is for supply for use in the above mentioned patient only.

4. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed usage constitutes use as an experimental drug.

5. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

6. The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.

7. Details of any suspected adverse drug reactions are reported to the TGA.

8. The TGA is notified of reasons for discontinuation should this occur.

9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for us, including dosage.

10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Aged Care
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

Yours sincerely

[redacted]

DELEGATE OF THE SECRETARY

15 July 2002