[redacted]

Type text here

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr[redacted]
[redacted]
[redacted]
[redacted]
[redacted] SA [redacted]

[redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received **21st December 2006** concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted], **DOB** [redacted]**/1963, URN** [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, and there may be implications regarding 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 **twelve (12) months** therapy of the above drug at a **dosage as per protocol**.

2. This approval is valid for up to **eighteen (18) months** from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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 sincere[redacted]

[redacted]

FOR [redacted]

DELEGATE OF THE SECRETARY

[redacted]

[redacted] [redacted] 21/12/2006 15:27 #082 P.001/001

3/1/07 [redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted]	DOB: [redacted] 1963.
MRN: [redacted]	SEX: [redacted]

Diagnosis: Crohn's Disease - perineal	Previous SAS No. (if applicable): Section 19(1)(a) letter dated 19 April 2006

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*

Patient has responded to infliximab for disabling perineal Crohn's. [redacted] now has an allergic reaction to infliximab, but has responded to the humanised anti TNFα receptor, adalimumab in open trial. Abbott are prepared to continue this without change.

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

Active* ingredient: Adalimumab.	Trade name /Device name: Humira
Company/supplier (State if imported): Abbott Australasia NSW.	
Dose form*: Pre-filled Syringes (2 pack)	Route of administration*: SC
Dosage*: 40mg	Duration of treatment: 12 months
Date of medical device procedure/use: Please commence asap	

Prescribing doctor details

Name: [redacted] *Initial* *Surname*	Hospital: [redacted]
Postal address (hospital or private): [redacted] South Australia *Postcode* [redacted]	[redacted] Phone [redacted] Fax number [redacted]
Signature & date: [redacted] 21/12/06	

Approved
As per PBS
- 12 mnth

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

[redacted]

21/1/07

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
[redacted]t
[redacted] VIC [redacted]

Dear [redacted]

Re: **ADALIMUMAB**

Thank you for your letter of 2nd November 2006 in response to my request for further information for supply of adalimumab for your patient [redacted] (Date of Birth: [redacted]/1969) under the SAS scheme for unregistered medications.

I draw your attention to the review article which accompanied your letter[1]. The article notes as follows:

Currently, ReA is better defined as an immune-mediated synovitis resulting from slow bacterial infections and showing intra-articular persistence of viable nonculturable bacteria and/or immunogenic bacterial antigens synthesized by metabolically active bacteria residing in the joint and/or elsewhere in the body.

The article also notes a case of reactive arthritis secondary to HIV which resulted in sepsis and death following the use of a TNF-α antagonist agent.

As you have not discussed the safety of the proposed use in your letter, I request you to please comment on the safety aspect especially in regard to the risk of flare up of serious infection. I'll then submit the information I receive from you to an internal group of senior medical officers for advice before a decision is made.

Further information about the supply of unapproved medicines can be obtained from the TGA website at http://www.tga.gov.au/unapp/index.htm.

I thank you and look forward to hearing from you.

Yours sincerely

[redacted]
Drug Safety & Evaluation Branch

09 November 2006

[1] Colmegna I, Cuchacovich R, Espinoza LR. HLA-B27-Associated Arthritis: Pathogenetic and Clinical Considerations. *Clinical Microbiology Reviews*; Apr. 2004, p.348-369.

[redacted]

[redacted]

T-902 P.001/001 F-510

T-360 P.002/002 F-984

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TGA THERAPEUTIC GOODS ADMINISTRATION

NON DATA ENTRY URGENT

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] 69 [redacted]

Diagnosis: REACTIVE ARTHRITIS

Previous SAS No.: —

Clinical justification for use of product *Include appraisal of seriousness of patient's condition; detail previous treatment and expected benefits from use of the product*: ACTIVE INFLAMMATION IN MULTIPLE LARGE JOINTS LEADING TO DAMAGE AND INCREASING LOSS OF FUNCTION

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

Trade name /Device name: HUMIRA.

Company/supplier: ABBOTT AUSTRALASIA.

Dose form*: INJECTION

Route of administration*: S/C.

Dosage*: 40mg

Duration of treatment: 6 Months (in first instance).

Prescribing doctor details

Name: [redacted]

Hospital: [redacted]

Postal address: [redacted]

Department:

[redacted]

VIC

[redacted]

Signature: [redacted]

27/7/06

Form no. 2950 (0105)

PTO

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]
[redacted] ACT [redacted]

[redacted],

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 15th June 2006 concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **/1956,** [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, and there may be implications regarding 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 **three (3) months'** therapy of the above drug at a **dosage as per sponsor's protocol**.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 accepts 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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]

[redacted]
DELEGATE OF THE SECRETARY

19 June 2006

15. JUN. 2006 12:48 [redacted]

[redacted] DATABASE PRODUCT 15/6/06

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted] DOB: [redacted]/1958

MRN: [redacted] SEX: [redacted]

Diagnosis: Inflammatory bowel disease

Previous SAS No. (if applicable): 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*: Inflammatory bowel disease – initial response to infliximab. Loss of response over time suggesting development of antibodies to infliximab

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

Active* ingredient: ADALIMUMAB

Trade name /Device name: HUMIRA

Company/supplier (State if imported): ABBOTT AUSTRALASIA

Dose form*: 40mg/0.8mL

Route of administration*: Subcutaneous

Dosage*: 80mg then 40mg monthly

Duration of treatment: Determined by response [redacted]

Date of medical device procedure/use: —

Prescribing doctor details

Name: [redacted] *Initial Surname*

Hospital: [redacted]

Postal address (hospital or private). The approval letter will be mailed to this address.: [redacted] ACT

Department: [redacted]

Phone: [redacted]

Fax number: [redacted]

Signature & date: [redacted] 15/06/06

Approved As per protocol - 3 months [redacted] 15/6/06

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Form no. 2950 (0405)

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]
[redacted] ACT [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received **8th June 2006** concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **/1982, URN [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, and there may be implications regarding 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:

- The approval is given for the supply of **three (3) months'** therapy of the above drug at a **dosage as per sponsor's protocol**.
- This approval is valid for up to **six (6) months** from the date of this letter or until revoked or until **Adalimumab (Humira)** is marketed in Australia, whichever is sooner.
- The approval is for supply for use in the above-mentioned patient only.
- 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.
- The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

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

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

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

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

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

- This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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

9 June 2006

[redacted]

001 57

[redacted]

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]
ACT [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received **8th June 2006** concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **/1982,** [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, and there may be implications regarding 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:

- The approval is given for the supply of **three (3) months'** therapy of the above drug at a **dosage as per sponsor's protocol.**
- This approval is valid for up to **six (6) months** from the date of this letter or until

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted] DOB: [redacted]1982

MRN: [redacted] SEX: [redacted]

Diagnosis: Crohn's disease - unresponsive to infliximab.

Previous SAS No. (if applicable): 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*: Patient is unresponsive to infliximab. [redacted] has developed infusion reactions presumably due to inactivating antibodies. It is possible that [redacted] would benefit from a different anti-TNF agent.

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

Active* ingredient: ADALIMUMAB

Trade name /Device name: HUMIRA

Company/supplier (State if imported): ABBOTT AUSTRALASIA

Dose form*: 160mg

Route of administration*: Subcutaneous inj^n

Dosage*: 160mg/80mg Week2

Duration of treatment: Depends on response

Date of medical device procedure/use: When approved

Approved

Approved

3 months

[redacted]

8/6/06

Prescribing doctor details

Name: [redacted] (Initial Surname)

Hospital: [redacted]

Department: [redacted]

Postal address (hospital or private). The approval letter will be mailed to this address.

[redacted]

ACT [redacted]

Phone: [redacted]

Fax number: [redacted]

Signature & date: [redacted] 7/6/06

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8783 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Form no. 2950 (0405)

NO. 609 P. 2

[redacted]

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
[redacted]
[redacted] QLD [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received **30th May 2006** concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] ([redacted] **1963,** [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, and there may be implications regarding 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:

- The approval is given for the supply of **six (6) months'** therapy of the above drug at a **dosage as per sponsor's protocol**.
- This approval is valid for up to **twelve (12) months** from the date of this letter or until revoked or until **Adalimumab (Humira)** is marketed in Australia, whichever is sooner.
- The approval is for supply for use in the above-mentioned patient only.
- 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.
- The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

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

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

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

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

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

- This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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]

[redacted]
DELEGATE OF THE SECRETARY

31st May 2006

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NON DATABASE PRODUCT
(1) 30/5/06

TGA THERAPEUTIC GOODS ADMINISTRATION

CATEGORY B FORM
SPECIAL ACCESS SCHEME

Commonwealth Department of 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] 1962.

Diagnosis: Crohns disease

Previous SAS No.:

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 crohns disease with enterc fistulas

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

Trade name /Device name: Humira.

Company/supplier: Abbott NSW (02)93849801

Rejected Approved

Dose form*: 40mg/0.8mL

Route of administration*: S/C.

Regular Drug

Dosage*: 40mg Q2weekly

Duration of treatment:

Prescribing doctor details

Available & marketed in Aust.

Name: [redacted]

Hospital: [redacted]

Postal address: [redacted] Brisbane

Department: [redacted]

Phone: [redacted]

Fax number:

[redacted]

Signature: [redacted] 25/5/6.

30/5/06

Form no. 2950 (0105)

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
[redacted]
[redacted] ACT [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 15th June 2006 concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **([redacted]/1985, [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, and there may be implications regarding 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 **three (3) months'** therapy of the above drug at a **dosage as per sponsor's protocol**.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 accepts 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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]

[redacted]
DELEGATE OF THE SECRETARY

19 June 2006

45

NON DATABASE PRODUCT (1) 15/6/06

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted] DOB: [redacted] 1985

MRN: [redacted] SEX: [redacted]

Diagnosis: Inflammatory bowel disease

Previous SAS No. (if applicable): 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*: Inflammatory bowel disease with the development of infusion reactions to infliximab therapy.

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

Active* ingredient: ADALIMUMAB

Trade name /Device name: HUMIRA

Company/supplier (State if imported): ABBOTT AUSTRALASIA

Dose form*: 1 40mg /0.8mL

Route of administration*: Subcutaneously

Dosage*: 80mg followed by 40mg each month

Duration of treatment: Determined by response

Date of medical device procedure/use:

Prescribing doctor details

Name: [redacted] *Initial Surname*

Hospital: [redacted]

Postal address (hospital or private). The approval letter will be mailed to this address.

Department: [redacted]

Approved

As per portal

3 months

[redacted] ACT [redacted]

Phone: [redacted]

Fax number: [redacted]

Signature & date: [redacted] 15/06/06

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Form no. 2950 (0405)

15/6/06

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
[redacted]
[redacted]
[redacted] SA [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 18th April 2006 concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted], **DOB** [redacted]**/1963, URN** [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, and there may be implications regarding 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 **six (6) months'** therapy of the above drug at a **dosage as per sponsor's protocol.**

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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]

[redacted]

DELEGATE OF THE SECRETARY

19 April 2006

[redacted]

NON DATABASE PRODUCT
18/4/06

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted]	DOB: [redacted] 1963.
MRN: [redacted]	SEX: [redacted]

Diagnosis: Crohn's Disease -perineal	Previous SAS No. (if applicable): 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:*

Patient has responded to infliximab for disabling perineal Crohns. [redacted] now has an allergic reaction to infliximab, but has responded to the humanised anti TNFα receptor adalimumab in open trial. Abbott are prepared to continue this without change.

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

Active* Ingredient: Adalimumab.	Trade name /Device name: Humira
Company/supplier (State if imported): Abbott Australasia NSW.	
Dose form*: Pre-filled Syringer (2 pack)	Route of administration*: SC
Dosage*: 40mg	Duration of treatment: 12 months
Date of medical device procedure/use: Please commence asap	

Approved
12 months
[redacted]
18/4/06
[redacted]

Prescribing doctor details

Name: [redacted] *Initial* *Surname*	Hospital: [redacted]
Postal address (hospital or private). The approval letter will be mailed to this address. [redacted] South Australia *Postcode* [redacted]	Department: Gastro enterology
	Phone: [redacted]
	Fax number: [redacted]
Signature & date: [redacted]	11/4/06

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

Dr [redacted]

[redacted]

[redacted]

[redacted] VIC [redacted]

Patient Category : [redacted]

26/12/2005

Drug: Adalimumab
Patient: [redacted] DOB [redacted]/1952
Supplier: Unknown
Dosage: As per protocol
Duration:3 months
Dose Form: Injection

THERAPEUTIC GOODS ACT 1989, S.19
EXEMTIONS FOR SPECIAL AND EXPERIMENTAL USES
APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME

Concerning your application to use the above drug in the treatment of the above patient on the grounds that there is no alternative therapy currently supplied in Australia, I, the medically qualified person named below, hereby provide a formal Notification of Approval. The proposed clinical use of this drug must be regarded both medico-legally and ethically as experimental. No assurance can be given as to the quality, safety and efficacy in the proposed usage. Your co-operation is required concerning sound data management.

Permission is given for the use of the drug in the above patient for the above duration subject to the following conditions: -

1. The doctor and patient, patient's parent or guardian accept responsibility for any adverse consequences of therapy;
2. The principles set out in the National Health and Medical Research Council's 'Statement on Human Experimentation' is observed;
3. Details of any suspected adverse drug reactions are to be reported to the Australia Drug Evaluation Committee;
4. The TGA be notified of reasons for discontinuation should this occur;
5. On completion of the treatment a detailed patient profile, before and after treatment, is to be submitted to the supplier of this product;
6. On completion of the treatment all remaining supplies of the above product be returned to the supplier;
7. The company supplying the drug accepts responsibility for any defects in the drug related to manufacture, distribution or directions for use including dosage.
8. Special Conditions: Nil

[redacted]

Drug Safety and Evaluation Branch
Doctor : Please forward a copy to your Chief Pharmacist

THERAPEUTIC GOODS ADMINISTRATION — SAS DATA ENTRY REPORT

SAS Number [redacted]

Evaluation Unit 4

Drug (Active Ingredient) ADALIMUMAB

Doctor [redacted]

Drug (Trade Name) HUMIRA

Tel. No. [redacted]

Company Name

Hospital Name [redacted]

Section/Department [redacted]

Postal Address

Patient's initials [redacted] Sex [redacted] Date of birth [redacted] Patient ID ?

Dosage 40mg s/c

Dosage form inj. s/c

Duration q 2/52 x 3 months

Route of administration s/c

Diagnosis Crohn's colitis

Previous/Current Therapy & other Comments

Monitoring

Special conditions

Change details

Approval YES ✓ NO

Delegate's Signature [redacted]

Date 26/12/05

No increase not contactable to give SAS No. - LL

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted] DOB: [redacted]952

MRN: SEX: [redacted]

Diagnosis: CROHN'S COLITIS

Previous SAS No. (if applicable):

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

[redacted] has intractable Crohns colitis. [redacted] is osteoporotic, has failed azathioprine therapy and is failing methotrexate therapy. A recent dose of infliximab was ineffective though [redacted] did respond originally. Remission is expected. Proctocolectomy is the alternative.

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

Active* ingredient: ADALIMUMAB

Trade name /Device name: HUMIRA

Company/supplier (State if imported): ABBOTT (AUSTRALIA) P/L.

Dose form*: Ampoule.

Route of administration*: Subcutaneous

Dosage*: 40 mg every other week

Duration of treatment: 3 months (initially)

Date of medical device procedure/use:

Prescribing doctor details

Name: [redacted] *Initial Surname*

Hospital: [redacted]

Department: [redacted]

Postal address (hospital or private).
The approval letter will be mailed to this address.

[redacted]
Victoria
[redacted]

Phone: [redacted]

Fax number: [redacted]

Signature & date: [redacted] 23/12/05

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Form no. 2950 (0405)

[redacted]

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]
[redacted] VIC [redacted]

Dear Dr [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 23rd December 2005 concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **(DOB [redacted]/1952)**

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, and there may be implications regarding 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 three (3) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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

4 January 2006

NON DATABASE PRODUCT

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted] DOB: [redacted] 1952

MRN: SEX: [redacted]

Diagnosis: CROHN'S COLITIS

Previous SAS No. (if applicable):

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*: [redacted] has intractable Crohns colitis. She is osteoporotic, has failed azathioprine therapy and is failing methotrexate therapy. A recent dose of infliximab was ineffective though [redacted] did respond originally. Remission is expected; Prednisolone daily is the alternative.

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

APPROVED 3 months

Active* ingredient: ADALIMUMAB

Trade name /Device name: HUMIRA

Company/supplier (Status if imported): ABBOTT (AUSTRALIA) P/L.

[redacted]

Dose form*: Ampoule.

Route of administration*: Subcutaneous

Dosage*: 40 mg every other week

Duration of treatment: 3 months (initially)

31/1/06

Date of medical device procedure/use:

Prescribing doctor details

Name: [redacted] *Initial Surname*

Hospital: [redacted]

Department: [redacted]

Postal address (hospital or private). The approval letter will be mailed to this address.

[redacted]

Victoria

[redacted]

Phone: [redacted]

Fax number: [redacted]

Signature & date: [redacted] 23/12/05

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

30.
46-2/46259

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
[redacted]
[redacted] QLD [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 14th December 2005 concerning approval to supply **Adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **(DOB** [redacted] **/1962) UR:** [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, and there may be implications regarding 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 twelve (12) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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

16 December 2005

①

URGENT + FAX REPLY PLEASE

TGA THERAPEUTIC GOODS ADMINISTRATION

CATEGORY B FORM
SPECIAL ACCESS SCHEME

Commonwealth Department of 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] /1962 URI [redacted]
Diagnosis	FISTULIZING CROHN'S DISEASE
Previous SAS No.	By Letter. No Number Issued.
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*	PREVIOUS RESPONSE TO ADALIMUMAB + FAILURE TO RESPOND TO AZATHIOPRINE + OTHER IMMUNOSUPPRESSION NEEDS TO COMPLETE / HAVE ONGOING THERAPY.

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	Trade name /Device name	HUMIRA
Company/supplier	ABBOTT		
Dose form*	40mg / 0.8mL syringe	Route of administration*	SC Injection
Dosage*	40mg 2nd weekly SC.	Duration of treatment	12 months (total)

Prescribing doctor details

Approved
Approved
Approved
12 months

Name	[redacted] *Initial Surname*	Hospital	[redacted]
Postal address	[redacted]	Department	[redacted]
	SOUTH BRISBANE [redacted]	Phone	[redacted]
		Fax number	[redacted]
Signature	[redacted]		8/12/05

Form no. 2950 (0105)

EO1

[redacted]

27.

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
C/- [redacted]
[redacted] QLD [redacted]

Dear [redacted]

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 13th December 2005 concerning approval to supply **adalimumab (Humira)** 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 (Humira)** for use in the treatment of your patient [redacted] **(DOB** [redacted] **/1985) UR:** [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, and there may be implications regarding 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 twelve (12) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to twelve (12) months from the date of this letter or until revoked or until **adalimumab (Humira)** 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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

16 December 2005

URGENT 25

NON DATABASE PRODUCT

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] UR: [redacted] DOB: [redacted]/1985

Diagnosis: Crohn's Disease

Previous SAS No.:

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 active Crohn's Disease not responsive to immunosuppression with terminal ileal, peri-anal and colonic involvement but not fistulizing. Previous good response to Adalimumab in clinical trial

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.

Trade name /Device name: HUMIRA

Company/supplier: ABBOTT

Approved

Dose form*: 40mg/0.8ml vial. ✓

Route of administration*: SC ✓

Dosage*: 40mg 2nd weekly SC ✓

Duration of treatment: 12 months. ✓

12 months

Prescribing doctor details

[redacted]

Name: [redacted]

Hospital: [redacted]

Postal address: [redacted]

Department: [redacted]

Approved

South Brisbane

Postcode [redacted]

Phone: [redacted]

Fax number: [redacted]

Signature: [redacted] 13/12/05

Form no. 2950 (0105)

2A

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]

Dr [redacted]
[redacted]
[redacted] QLD [redacted]

Dear [redacted],

Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 19th October 2005 concerning approval to supply **Adalimumab (Humira** 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 (Humira)** for use in the treatment of your patient [redacted] **(DOB** [redacted] **/1962) UR** [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, and there may be implications regarding 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 three (3) months' therapy of the above drug at a dosage of 40mg, every 2 weeks, subcutaneous injection.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until **Adalimumab (Humira)** 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 use, including dosage.

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

11. This approval provides an exemption from the Therapeutic Goods legislation in order to allow supply of this unapproved product in the circumstances described. Other legislation, including any relevant State or Territory legislation, must still be complied with.

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 Ageing
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

19 October 2005

[redacted]

22

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] (1962 [redacted]

Diagnosis Fistulising Crohn's Disease

Previous SAS No.

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*

Multiple enterocutaneous fistulae with significant systemic symptoms and previous good clinical response (12 months use as part of clinical trial). Noted [redacted]

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

Trade name /Device name HUMIRA

Company/supplier ABBOTT

Dose form* 40 mg vial.

Route of administration* Subcutaneous inj^{n}

Dosage* 40 mg 2nd weekly

Duration of treatment 12 months + ~~3 months~~ [redacted]

Prescribing doctor details

Name [redacted] *Initial Surname*

Hospital [redacted]

Postal address [redacted]

Department [redacted]

Phone [redacted]

SOUTH BRISBANE Post[redacted]

Fax number [redacted]

Signature [redacted] 18/10/05

approved ADALIMUMAB / HUMIRA injection dose = 40 mg, every 2 weeks subcutaneous injection 3 months' initial treat[redacted]

Form no. 2950 (0105)

2002/46259.

21

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Dr [redacted]
[redacted]
Hobart [redacted]

Dear Dr [redacted]

Re: Special Access Scheme Approval - Adalimumab

I refer to your request received 4 August 2004 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] **(DOB** [redacted] **1990).**

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 therapeutic good as defined in the *Act*, 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, and there may be implications regarding 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 of 24mg/m^{2}BSA subcutaneously every 2 weeks

2. Doses are to be given in a suitably equipped medical facility under the supervision of medical personnel trained in resuscitation, until such time as it is clear that the patient is not at risk of anaphylaxis.

3. This approval is valid for up to twelve (12) months from the date of this letter.

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

5. The product is used within the context of fully informed consent. The proposed usage is not in accordance with the conditions of registration of **Adalimumab** and constitutes use as an experimental drug.

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

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

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

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

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

11. 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 Ageing
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

11 August 2004

NON DATABASE PRODUCT

19

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CATEGORY B FORM
SPECIAL ACCESS SCHEME

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient details

Patient's initials: [redacted] DOB: [redacted] 90 → [redacted]

MRN: SEX: [redacted]

Diagnosis: Juvenile chronic arthritis

Previous SAS No. (if applicable):

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: Qualified for Etanercept via HIC criteria – unfortunately had severe anaphylactoid response to Etanercept.

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

Active* ingredient: Adalimumab

Trade name /Device name: Humira

Company/supplier (State if imported): ABBOTT

Dose form*: SC injection

Route of administration*: SC

[redacted] after
Dosage*: 40mg SC every 2 weeks
24 mg/m² BSA

Duration of treatment: 12 months

[redacted] te of medical device procedure/use

Prescribing doctor details

Name: [redacted]

Hospital: [redacted]

Department: [redacted]

Postal address (hospital or private).
The approval letter will be mailed to this address.

[redacted]

HOBART

Phone: [redacted]

Fax number: [redacted]

Signature & date: [redacted] 5/8/04

Approved
24 mg / ~~kg~~ m² BSA subcutaneously every 2 weeks for 6 months.
Doses to be given under supervision of medical personnel trained in resuscitation, with resuscitation equipment to hand, until it is clear that the patient is not [redacted]
[redacted] 11-8-04

Fax (medicines): 02 6232 8112 Fax (medical devices): 02 6232 8785 Mail: SAS Officer, TGA, PO Box 100, Woden ACT 2606

Form no. 2950 (0405)

- Company aware that this is for off label use so SAS approval is required for them to supply for what they consider to be pediatric pt.
- Weight 35kg, Plan to use 1/2 adult dose (ie 20mg)
- Dr F has spoken to medical director of Abbott, but has not seen any clin trial reports/case reports of paediatric usage. [redacted] 11-8-04

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

Dr [redacted]
[redacted]
[redacted] NSW [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] **(DOB [redacted]/1979).**

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.

(6)

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 [redacted]

[redacted]

DELEGATE OF THE SECRETARY

15 July 2002

[redacted] 003

[redacted] Medical Officer, [redacted]

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] DOB [redacted] 79. [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] Initial Surname	Hospital	[redacted]
Postal address	[redacted]	Department	[redacted]
	[redacted]	Phone	[redacted]
	NSW	Fax number	[redacted]
	[redacted] Postcode		
Signature	[redacted]		7/7/02

Form no. 2950 (0105)

[redacted]