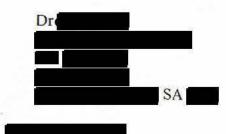


Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 21<sup>st</sup> 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 DOB (1963, URN)

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.
- 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 <u>unregistered</u> 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.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804

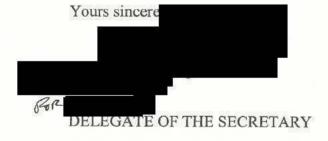
- 7. Details of any suspected adverse drug reactions are reported to the TGA.
- 8. The TGA is notified of reasons for discontinuation should this occur.
- 9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including 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.

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.







# Asstralian 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's initials:	DOB:	11963.
when m. W		V 1403.
MIRN:	SEX:	
Diagnosis Crohns Disease - perineal		Sas No. Section 19 (1)(a) letter dated 19 April 2006
include appraisal of seriousness, of patient's condition; detail revious treatments and inflict mab, but h	now has on as responded to f	allergic reaction to helpmanised anti TNTX are preputed to contin
roduct details  Attach efficacy and safety data to sup  "Complete for medicines only,	pport proposed use of the product	and details of intended monitoring C
Active* Adalimumab.	Trade name /Device name	Humira
Company/supplier Abboth Australes 116 (State if imported) NSW.	a	197
Dose form + Pre-filled Synger (2 pocks)	Route of administration*	S C
Dosage* 40 mg	Duration of treatment	12 months
	(A)	
te of medical device procedure/use Please co	ommence asap	
escribing doctor details	ommence asap	
	Hospital	e
escribing doctor details		
Name  Initial Surname  Postal address (hospital or private).		
Name  Initial Surname  Postal address (hospital or private).	Hospital	

2/1/67



Department of Health and Ageing Therapeutic Goods Administration



#### Re: ADALIMUMAB

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

I draw your attention to the review article which accompanied your letter<sup>1</sup>. 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- $\alpha$  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 <a href="http://www.tga.gov.au/unapp/index.htm">http://www.tga.gov.au/unapp/index.htm</a>.

I thank you and look forward to hearing from you.

Yours sincerely

Drug Safety & Evaluation Branch

09 November 2006

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au Telephone: 02 6232 8444 Facsimile: 02 6232 8605 ABN 40 939 406 804

<sup>&</sup>lt;sup>1</sup> Colmegna I, Cuchacovich R, Espinoza LR. HLA-B27-Associated Arthritis: Pathogenetic and Clinical Considerations. Clinical Microbiology Reviews; Apr. 2004, p.348-369.

# CATEGORY B FORM SPECIAL ACCESS SCHEME



tient details			
Patient details			
(initials, II) or URN, DOB, Sex)		69	
Diagnosis 2	FACTIVE AR	THE ITIS Previous	s SAS No.
Clinical justification			
for use of produ include appraisal	GET TO TVE	INFLAMORTIO	
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evious areamens p	AND INC	REASING LOS	S OF FUNCTION
expected benefits fro use of the produ	et		4 / 2
25W 92			
odner details A	tlach efficacy and sofaty data to s	upport proposed use of the preduct	and details of intended monitoring
	egime. *Complete for medicines of	only.	
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edient	ALIMAN AS	/Device name	HUMIRA-
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	Supplier ABBOT	Rouse of administration*	57c-
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PTO



# Department of Health and Ageing Therapeutic Goods Administration



## Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 15<sup>th</sup> 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 /1956,

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.

- 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.
- The product is used within the context of fully informed consent. The product is currently <u>unregistered</u> 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.

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



DELEGATE OF THE SECRETARY





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Australian Government

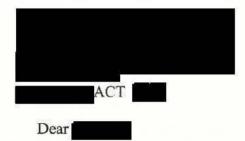
SPECIAL ACCESS SCHEME

Department of Health and Ageing Therapentic Goods Administration

Supervision of the same	1 200-1200 000 20		T CLEARLY AN	D COME L	GIN AND DAY	720210
Patient detai			DOB:	/14	758	
MRN:			SEX:			
Diagnosis	Inflamm	atony bowel	disease	Previous (if appl	SAS No.	N/A
previous treatm expected bem	f product praisal of f patient's on; detail ments and	ammatory l ximab. lopment o	losof r	reponse		resionse to me suggesting
Product deta		and safety data to su medicines only.	pport proposed use	of the product	and details of in	ended monitoring
Active* ingredient	ADALIA	NUMAB	100	rade name	HUMI	RA
Company/su (State if impo	applier orted)	BBOTT	AUSTRA	LASA.	IA	
Dose form*	40mg/1	1.8mL	Route of admir	nistration*	Sul	autaneous
Dosage*	80mg f	hen 40mg	Duration of	treatment	Determ	ined by res
Date of medic	al device procedure	/use				
Prescribing d	loctor details					
Name In	itial Surname			Hospital		
	ostal address (hospi ne approval letter w		address. De	epartment		
					8	
				Phone		
	A	C1 -	Far	x number		



# Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 8<sup>th</sup> 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 /1982, URN

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.

- 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 <u>unregistered</u> 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.

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".

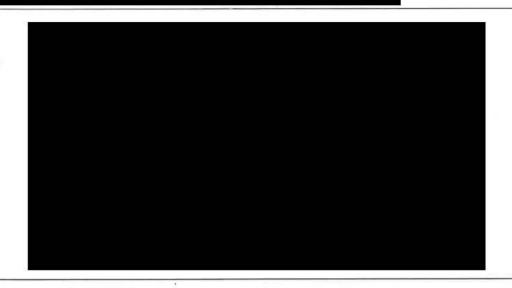
Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

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



DELEGATE OF THE SECRETARY





Department of Health and Ageing Therapeutic Goods Administration



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 patier ts.

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 /1982,

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapoutic 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.

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



Department of Health and Ageing Therapeutic Goods Administration

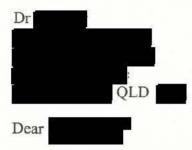
CATEGORY B FORM SPECIAL ACCESS SCHEME

	riols	DOB;	1987
Patient's init	lato-	SEX:	
Diagnosis	Craha's disease - u to infliximab.		rious SAS No. N/A applicable)
Include ap seriousness of condit previous treat expected bet	of product tatien; 13 u popraisal of infusion reach infusion reach it is possible to product the product infusion reach its possible to po	ole that would be	to inactivating antibo
Product det	Attach efficacy and safety d *Complete for medicines on		duct and details of intended monitoring
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Company/s (State if imp	supplier ABBOFT	AUSTRALASI.	A
Dose form*	160 mg	Route of administration	* Subcutaneous in
Dosage*	160mg/80mg	Week 2 Duration of treatmen	ne Depends on Respons
Date of medi	cal device procedure/use	hen approved.	
	doctor details		
Prescribing			
Name	пира зилите	Hospitz	d
Name 7	Postal address (hospital or private The approval letter will be maile	te).	
Name 7	Postal address (hospital or privat	te).	
Name 7	Postal address (hospital or privat	te).	at .
Name 7	Postal address (hospital or privat	te). d to this address.  Department	e

7. '4 009 ON Form no. 2950 (0405)



Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 30<sup>th</sup> 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 [1963,]

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 <u>unregistered</u> 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.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804

- 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.

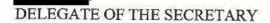
The Parliamentary Secretary to the Minister for Health and Ageing Parliament House CANBERRA ACT 2600

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

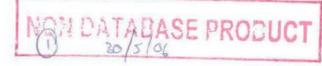
Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

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



31st May 2006



THERAPEUTIC GOODS ADMINISTRATION

#### CATEGORY B FORM SPECIAL ACCESS SCHEME



Health and Aged Care

Form no. 2950 (0105)

# PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS Patient details Patient details (initials, ID or URN, DOB, Sex) Previous SAS No. Diagnosis 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 Attach efficacy and safety data to support proposed use of the product and details of intended monitoring Product details regime. \*Complete for medicines only, -dalimuma! Active\* Trade name ingredient /Device name Company/supplier Abb of Dose form\* Route of administration\* Dosage\* Duration of treatment Prescribing doctor details Hospital Name **Postal** Department address Phone Fax number 25151 Signature 3/6/5



Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 15<sup>th</sup> 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 (1985, 1985, 1985)

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.

- 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 <u>unregistered</u> 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.

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



DELEGATE OF THE SECRETARY



CATEGORY B FORM
SPECIAL ACCESS SCHEME

Department of Health and Ageing Therapentic Goods Administration

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

	ls						
Patient's initi	als:			DOB:	19	85	
MRN:				SEX;			
Diagnosis	Inflamm	atory bowe	l disease	,		s SAS No.	N/A
previous treatm expected beni	product praisal of patient's on; detail nears and	flammator infusion	sea ction		e with		development
Product deta		cacy and safety de for medicines on		proposed use of	the product	and details o	f intended monitoring.
Active* ingredient	ADAL	MUMAI	3		de name	HUM	IRA
Company/su (State if impo	applier orted)	ABBOTT	T AUS	TRAL	ASIF	-)	
Dose form*	1 40mg	10.8mL	Ro	ute of admini:	stration*	Sub	autoneously.
Dosage*	80mg	followed by	40 mg	Duration of t	reatment		ned by respose
Date of medic	al device proce	with dure/use					
Prescribing (	loctor details		-				
Name In	itial Surname			1	Hospital		
		ospital or privater will be maile		ess. Dep	partment		
^					Phone		
		ACI	-	Fax	number		
	Signatur & da						15 '06'06



Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 18<sup>th</sup> 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 DOB //1963, URN

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.

- 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 <u>unregistered</u> 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.
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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".

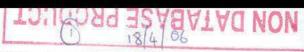
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Yours sincerely

DELEGATE OF THE SECRETARY

19 April 2006





# Australian Government Department of Health and Ageing Therapentic Goods Administration

# CATEGORY B FORM SPECIAL ACCESS SCHEME

# PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Patient's initi	als:	DOB:	11963	• •
MRN:		SEX:		
Diagnosis	Crohns Disease -perineal		vious SAS No. If applicable)	N/A.
previous treatn expected ben use of th	product rate thus representations and effis from e product receptor, adali	esponded to inflix hns. now has it has responded to myrrab in open trail.	on allergic o Helmani Abbott are pr	reaction to red onto TNT a repaired to contin
Product deta	*Complete for medicines only	a to support proposed use of the pi ,	roduct and details of	intended monitoring., C
Active*	Adalimumab.	Trade na /Device na	(1) (1) (1) (1) (1)	e
Company/su (State if imp		dosia		
Dose form*	Pre-filled Synnger (2	pocle) Route of administration	on* S	٠
Dosage*	40 mg	Duration of treatm	ent 12 m	on-ths
Date of medic	al device procedure/use Plan	tse commence asay	9	
Prescribing of	loctor details			4
Name In	itial Surname	Hosp	ital	
P	ostal address (hospital or private he approval letter will be mailed	to this address. Departm	ent Ciarho es	terdogy
	south Australia	Pho	one _	200 - 32-0 of
	Pos	tcode Fax num	ber	
	Signature & date	(1)		11 1111



# Department of Health and Ageing Therapeutic Goods Administration



Patient Category : Here; 26/12/2005

Drug: Adalimumab

Patient: DOB /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: -

- The doctor and patient, patient's parent or guardian accept responsibility for any adverse consequences of therapy;
- 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;
- 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

Drug Safety and Evaluation Branch

Doctor : Please forward a copy to your Chief Pharmacist

# THERAPEUTIC GOODS ADMINISTRATION

# SAS DATA ENTRY REPORT

SAS Number	Evaluation Unit 4
Drug (Active Ingredient)	FOALIMUMAB
Drug (Trade Name)	HVMINA Tel. No.
Company Name	
Hospital Name	
Section/Department	
Postal Address	
Patient's initials	Sex Date of birth Patient ID
Dosage	40mg 5/c Dosage form 17.5/c
Duration	9, 2/52 × 3 months Route of 5/C
Diagnosis	Crohis colotis
Previous/Current Therapy & other Comments	
Monitoring	
Special conditions	
Change details	
Approval YES	NO NO
Delegate's Signature	Date 26/12/05
n	1 110 L = SAR NO -



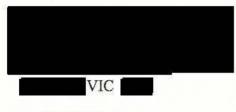
Department of Health and Ageing Therapeutic Goods Administration

## CATEGORY B FORM SPECIAL ACCESS SCHEME

	PLEASE USE BLACK PEN, PRINT	CLEARLY AND COMPLE	ETE ALL SECTIONS
Patient deta	ils		ri7
Patient's init	ials:	\$ 400	52
MRN:		SEX:	
Diagnosis	CROHN'S COLITIS		s SAS No.
Include up seriousness o condit previous treat expected bes	opraisal of has facled azather form detail methodreate the	hough did	
Product det	nils Attach efficacy and safety data to supp	port proposed use of the product	and drivils of intended monttoring.
Active*	*Complete for medicines only.  ADALIMUMAB	Trade name /Device name	HUMRA
Company/s (State if imp		tura) PIL.	
Dose form*	Ampoule.	Route of administration*	Subartaneous
Dosage*	40 mg every other week	Duration of treatment	3 months (includly)
Date of medi	ical device procedure/use		
Prescribing	doctor details	And the second s	
Name	ітікні Зипате	Hospital	
·=	Postal address (hospital or private). The approval letter will be mailed to this	address. Department	
, and a second		24	
İ	Victoria	Phone	
		l'ax number	
	Signature & date		23,12,05
far (modicine	(a): 02 6232 8112 Fax (medical devices): 02	2 6232 8785 Mail: SAS Office	cer, TGA, PO Box 100, Woden ACT 2606



Department of Health and Ageing Therapeutic Goods Administration



Dear Dr

Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 23<sup>rd</sup> 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 [DOB]/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.
- 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 <u>unregistered</u> 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.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804

- 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.
- 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.

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

DELEGATE OF THE SECRETARY

January 2006



NON DATABASE PROPERTE FORM

SPECIAL ACCESS SCHEME

Department of Health and Ageing Therapeutic Goods Administration

Patient's ini	rials:	DOB:	1952	
MRN:	.1d15.	SEX;		
1724		- · · ·		
Diagnosis	CROHN'S COLITIS		Previous SAS No. (if applicable)	
Clinical jus		able Cohu	s colilis: She	us osleoparotio
Include a	ppreisal of Landa land a 70th			***
	tion: detail methologicate th			
previous trea expected be use of t	nefits from load in effective	Though.	ded responde	regenally
Product de		ipport proposed use of	the product and desails of in	ended mundoring.
Active*	ADALIMUMAB		de name HUMR	A
5X>				
Company/		CALLA) PIL	•	**************************************
Dose form*	Ampoule.	Route of admini	stration* Subaut	aneous
Dosage	* 40 mg every other wee	(Auration of t	realiment 3 suppli	is (initially
Date of med	lical device procedure/use			
Prescribin;	g doctor details			
Name	Initial Surname		Hospital	
	Postal address (hospital or private). The approval letter will be mailed to the	nis address. De	partment	
	Victoria		Phone	
17.00		Fax	number	
			1	



Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 14<sup>th</sup> 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 [OOB]/1962) UR:

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.

- 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.
- 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 <u>unregistered</u> 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.

- 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.

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

DELEGATE OF THE SECRETARY

H December 2005

# URGENT + FAX REPLY



**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 11962 UR URN, DOB, Sex) FISTULIZING CROHN'S DISEASE Previous SAS No. Diagnosis Clinical justification TO ADALIMUMAS PRELIOUS RESPONSE for use of product Include appraisal of TO seriousness of patient's condition; detail IMMUNOSUPPRESSION previous treatments and expected benefits from use of the product COMPLETE HAVE ONGOING NEEDI THERAPY Attach efficacy and safety data to support proposed use of the product and details of intended monitoring Product details regime. \*Complete for medicines only. HUMIRA Trade name Active\* SAMUMIJAGA ingredient Device name Company/supplier ABBOTT Injection 40 ma Dose form\* Route of administration\* Symmae Duration of treatment Dosage\* weelsley Prescribing doctor details Hospital Name Postal Department address Phone Fax number SOUTH BRISBANE 8112105 Signature

Form no. 2950 (0105)



Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval - Adalimumab (Humira)

I refer to your request received 13<sup>th</sup> 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 (DOB /1985) UR:

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.

- 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.
- 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 <u>unregistered</u> 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.
- 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.
- 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.

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

DELEGATE OF THE SECRETARY

December 2005



P. 01

Patient d	etails	
	nt: details ls, ID or UR: 1985	
Diagnos	is Crohn's Disease Previous SAS No.	
for us Include seriousnes con	justification se of product active crohn: organization sof patient's distion; detail tentments and terminal iteal, per- and and colonice	
expected use o	fine product Previous good response to Adahimmab in a	lin
Product d	A CONTRACT OF THE PARTY OF THE	
Active* ingredient	ADALIMUMAS. Trade name HUMIRA	
į	Company/supplier ABSOTT	POR COLO
Dose form*	40mg/0.8ml Vial. Route of administration* SC	
Dosage*	young and weekly SC Duration of treatment 12 months.	-
Prescribin	g doctor details	
Name	Hospital	
rostar address	Department	
	South Brisbane Phone	
	Postcode Fax number	
	Signature 13/12/0	2,
	Form no. 2950 (0	ก่สกต



# Department of Health and Ageing Therapeutic Goods Administration



Re: Special Access Scheme Approval – Adalimumab (Humira)

I refer to your request received 19<sup>th</sup> 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 (DOB /1962) UR

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.

- 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.
- The product is used within the context of fully informed consent. The product is currently <u>unregistered</u> 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.

- 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.

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.

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Yours sincerely

DELEGATE OF THE SECRETARY

19 October 2005

# CATEGORY B FORM SPECIAL ACCESS SCHEME



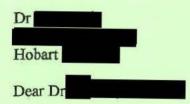
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Patient det	2119		
Patient (initials, URN, DOB	(D) or	1962	
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Clinical jus			es fistulal
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Product deta	Attach efficacy and safety data to sup regime, *Complete for medicines onl		uct and details of intended manitoring
Active*	ADALIMUMAJ	Trade name	44/11/11/11/11
Cor	mpany/supplier ABBO	ГТ	
se form*	Houng wal.	Route of administration*	Subcutaneous inj
Dosage*	tomg 2 weekly	Duration of treatment	12 mondhs +
rescribing d	octor details	-	3 month
Name Ini	na! Surname	Hospital	
Postal		Department	
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2	DUTH BRISBANE POUR	Fax number	
	Signature		18/10/05
rover 1	ADALIMUMAS/HUMIRA	injection	Form no. 2950 (0105)
a	ose 2 40 mg, ever	7 Lucks	1 1 100

2002/46259



## **Australian Government**

Department of Health and Ageing Therapeutic Goods Administration



## 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 (DOB 1990).

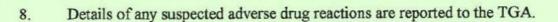
This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. No assurance is given by the Therapeutic Goods Administration as to the quality, safety or efficacy of this therapeutic good as defined in the *Act*, in the proposed usage.

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<sup>2</sup>BSA subcutaneously every 2 weeks
- 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.
- This approval is valid for up to twelve (12) months from the date of this letter.
- 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
  proposed usage is not in accordance with the conditions of registration of
  Adalimumab and constitutes use as an experimental drug.
- The doctor and patient or patient's guardian accepts responsibility for any adverse consequence of therapy.
- The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au Telephone: 02 6232 8111 Facsimile: 02 6232 8112 ABN 40 939 406 804 2)





- 9. 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.
- 11. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

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

DELEGATE OF THE SECRETARY

// August 2004



CATEGORY B FORM

Department of Health and Ageing Therapeutic Goods Administration SPECIAL ACCESS SCHEME



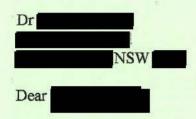
5	Patient details		1,40,40		
	Patient's initials:		DOB:	90 -	
	MRN:		SEX:		
	Diagnosis Juvenila attr	chromi		s SAS No. licable)	
	Clinical justification for use of product Include appraisal of seriousness of patient's		for Eta	nercipt - unfot	renaldy
900	condition; detail previous treatments and expected benefits from use of the product	i i i i i i i i i i i i i i i i i i i	e lang Etane	rept-	<u> </u>
	Product details Attach efficacy and s *Complete for medic	afety data to support pro ines only.	posed use of the product	and details of intended m	onitoring
	Active* A dali mu	onab	Trade name /Device name	Humira	<b>~</b>
	Company/supplier (State if imported)	)·17			
	Dose form* Sec. mye	Rout	e of administration*	SC	
	Dosage* 40mg	ceren D	uration of treatment	12000	ulla
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	te of medical device procedure/use				
-	Prescribing doctor details				
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Approved					
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to hourd, Pa	x (medicines): 02/6232 8112 Fax (med	lical devices): 02 6232 8	785 Mail: SAS Office	er, TGA, PO Box 100, Wo	den ACT 2606
clear that	the Companies regul	ned for the	t this is for	off last they no	53050 10005 de de la tric p
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17 miles	1-8-04/ Seen any 11	elin frial repor	to / case ignor to	of pardiatic	usage.

new file sequested 19.7



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





#### 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 (DOB 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.

- 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 <u>unregistered</u> 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.
- 6. The principles set out in the "National Statement on Ethical Conduct in Research Involving Humans" are observed.



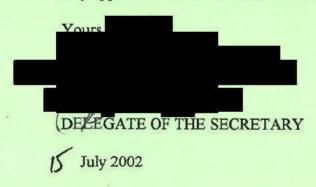
- 7. Details of any suspected adverse drug reactions are reported to the TGA.
- 8. The TGA is notified of reasons for discontinuation should this occur.
- 9. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for us, including dosage.
- 10. The product should be used in accordance with the treatment protocol provided to the TGA with the request.

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.



TG A THERAPEUTIC ROODS ADMINISTRATION

# CATEGORY B FORM SPECIAL ACCESS SCHEME

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