Annexure 2

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

Drug Safety & Evaluation Branch
Telephone: 02 6232 8113
Facsimile: 02 6232 8140

Health and Aged Care

Application Number: [Application No.]
Clin File: [Fil No.]
Chem File:[DE Chem / BIOL File No.]

The Managing Director
[COMPANY]
[ADDRESS 1]
[ADDRESS 2]

Attention: [Reg Affairs Officer]

Dear Sir/Madam

I refer to your application dated [DATE OF APPLICATION] for the registration of [PROPRIETARY NAME] ([CHEMICAL NAME]) in the Australian Register of Therapeutic Goods (ARTG) under the provisions of the Therapeutic Goods Act 1989 ("the Act").

Evaluation of your application (**[Application No.]**) has been completed.

Approval is now granted under Section 25(3) of the Act for the registration of [Proprietary Name] [Dose Form] containing [Drug] [Strength] for the indications stated herein (see below).

Supply is not permitted until the/each therapeutic good is registered.

Registration will not be effected until your company has agreed in writing to the description of the goods as detailed in this letter. Registration will commence on the day specified in the Certificate of Registration. You should complete all necessary steps to effect registration within three months of the date of this letter. Please confirm in writing that the product details contained in this letter are accurate in accordance with your application and any amendment properly notified during the course of the evaluation.

All separate and distinct goods within the meaning of Section 16(1) of the Act that have been approved following this evaluation are included in this registration approval.

For the purposes of Section 28 of the Act (Conditions of registration or listing) registration of each good described in this approval is subject to the following specific conditions:

CONDITIONS

1. **THE GOODS MUST CONFORM WITH THE FOLLOWING DESCRIPTION, MANUFACTURING INFORMATION, PRODUCT DETAILS, INDICATIONS, PRODUCT INFORMATION AND CONSUMER PRODUCT INFORMATION.**

DESCRIPTION OF GOODS FOR ACCEPTABILITY TO SUPPLY

NAME: [Proprietary name] [Drug] [Dose Form]

MANUFACTURER INFORMATION:

MANUFACTURER:
STEP(S):

MANUFACTURER:
STEP(S):

PRODUCT DETAILS

PRODUCT PROPRIETARY NAME:

PRODUCT GENERIC NAME:

PACK SIZE:

POISON SCHEDULE:

DOSAGE FORM:

ADMINISTRATION ROUTES:

CONTAINER TYPE:

VISUAL IDENTIFICATION:

STERILE: Yes/No

STERILISATION TYPE:

ANIMAL ORIGIN: Yes/No

Type of animal/insect/microbe:

FORMULATION:

Active ingredients:

Excipients:

Proprietary ingredients:

SHELF LIFE: (The potency of this product lies between ... - ...% of the labelled content of ... during its approved shelf life.)

Time:
Temperature:
Other Conditions:

INDICATIONS:

PRODUCT INFORMATION:

The text of the Product Information submitted with your letter of [Date PI Cleared] is considered satisfactory. The approved document is attached to this letter as Attachment 1.

PATIENT INFORMATION:

You are reminded that in accordance with Regulation 9(A) of the Therapeutic Goods Regulations a Patient Information document is required to be available for supply to the patient or agent. The format of this document is set out in Schedule 12 of the Regulations. The Patient Information document submitted with your letter of ... {insert date} is considered to meet the format as presented in Schedule 12 and not to contain any statement contrary to the approved Product Information.

You are reminded that there is a continuing obligation to ensure that at all times the patient information document (Consumer Medicine Information - CMI) complies with the statutory requirements. Following amendment of the Product Information, any changes needed to the patient information to ensure consistency with the Product Information must be made within 3 months of the approval or notification of the change to the Product Information. In the case of changes relating to the safety or safe use of the product, more rapid change of the patient information may be warranted.

2. THE STANDARD CONDITIONS APPLICABLE TO ALL REGISTERED GOODS ARE TO BE FOUND AT ATTACHMENT 2

3. SPECIAL CONDITIONS APPLYING TO THIS PRODUCT

(1) The Therapeutic Goods Administration Laboratories Branch (TGAL) is to be notified immediately the first production batches of this/these products are available for official sampling, under the terms of Regulation 24 of the Therapeutic Goods Regulations. This information should be sent to the Director, Therapeutic Goods Administration Laboratories Branch, PO Box 100 WODEN ACT 2606.

(2) Appropriate quantities of the reference material for the active ingredient, as well as of precursors, degradation products and other impurities for which limits are set in the

finished product specifications are to be provided free of charge to the TGA, if required by TGAL.

(3) Proposed changes to the approved chemical, pharmaceutical and biological details and specifications should be forwarded for evaluation by the Drug Safety and Evaluation Branch (DSEB) and must be approved prior to implementation, apart from a self-assessable change or a change which can be notified to the DSEB or the Australian Register of Therapeutic Goods (ARTG) as detailed in Appendices 7 and 8 to the document entitled:

Australian Guidelines for Registration of Drugs, Vol 1 - Prescription and Other Specified Drug Products, 2nd Edition (AGRD1). [Appendices 7 and 8 are entitled, respectively , Changes to Drug Products - Is Notification or Prior Approval Required? and Changes which may be made to Pharmaceutical Aspects of Drug Products without Prior Approval ('Self-Assessable Changes')]. Changes to test methods and specifications may also be required following laboratory analysis of the product by TGAL.

Please note: approved chemical, pharmaceutical and biological details and specifications include all those details on which approval is based in relation to sponsor, finished product details, formulation, active raw materials, excipients, manufacturing process, quality control, and packaging. (Refer to the AGRD Appendices 7 and 8 specified above.)

(4) The Product Information (reference 4.20 AGRD1, 2nd edition) must meet with the TGA's approval at all times. With the exception of safety related changes that further restrict the use of the product, which must be notified to the TGA within five working days, any proposed changes to the approved text must be submitted and be approved by the Administration prior to distribution.

The safety related changes referred to above are defined as those that delete an indication or reduce the patient population, or add a warning, precaution, adverse reaction or contraindication.

The Product Information should conclude with a statement that it has been approved by the Therapeutic Goods Administration (TGA), citing the date of the approval letter. **Two copies of the final printed version of the Product Information are to be forwarded to the Drug Safety and Evaluation Branch.** For all injectable products the Product Information must be included with the product as a package insert.

Abridged Product Information must accurately reflect the approved Product Information, including safety related statements, but may be a paraphrase or precis of the approved Product Information.

(5) Promotional material (other than Product Information) relating to the registered good must comply with the requirements of the Code of Conduct of the Australian Pharmaceutical Manufacturers' Association.

(6) The actual date of commencement of supply is to be notified to the Director, Drug Safety and Evaluation Branch, in addition to notifying the ARTG. Should it be decided not to proceed to supply, notification to this effect should be provided.

(7) Post marketing reports are to be provided annually until the period covered by such reports is not less than three years from the date of this approval letter. No fewer than three annual reports are required. The reports are to meet the requirements for Periodic Safety Update Reports as described in ICH document Topic E2 (CPMP/ICH/228/95). Unless agreed separately between the supplier who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 15 calendar months after the date of this approval letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report. The annual submission may be made up of two Periodic Safety Update Reports each covering six months. If the sponsor wishes, the six monthly reports may be submitted separately as they become available. Submission of the report must be submitted within the sixty days of the data lock point for the report (or, where applicable, the second of the two six monthly reports), as required by CPMP/ICH/228/95.

In the absence of the availability of Periodic Safety Update Reports, a report is to be provided annually for three years from the date of approval which shall include details of:

(a) all investigational studies relating to the chemical and physical properties, including stability of the drug under storage;
(b) all pharmacological and toxicological studies conducted or reported, including studies recorded in scientific literature;
(c) all clinical studies conducted or reported in Australia or abroad, including studies recorded in scientific literature, and a bibliography of these reports;
(d) (i) all suspected adverse reactions or similar experiences occurring in Australia received, including full clinical details (For adverse reactions occurring outside Australia, see Appendix 20 of AGRD1, 2nd Edition. Note: for the three year period specified, reporting is mandatory); and,
(ii) significant foreign adverse events which may have implications for the product information documents for this chemical entity.

Each report is to be accompanied by a statement of the amount of each presentation of the product issued in Australia in the same period (or a period up to the same data lock point.).

The above information should be forwarded to the TGA at the appropriate time.

(8) Details of the distribution of the drug including quantities and forms of products distributed and related batch numbers should be supplied on request while the drug remains on the ARTG.

You should be aware that:

Pursuant to the Customs (Prohibited Imports) Regulations a current permit to import is required for antibiotics and may be obtained from:

The Antibiotics Import Officer
Chemistry Section
Therapeutic Goods Administration Laboratories.
Telephone: (02) 6232 8452; Facsimile: (02) 6232 8450

or

This drug is of biological origin and a permission to import should be requested from:

Australian Quarantine and Inspection Service
Department of Primary Industries and Energy
GPO Box 858
CANBERRA ACT 2601
Telephone: (02) 6272 4578 Facsimile: (02) 6273 2097

or

The active ingredient of this product is listed in the 8th Schedule of the Customs (Prohibited Imports) Regulations and a current permission to import is attached. (See also Condition No 20 of the attached Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989).

or

You should contact the Treaties Monitoring Section, Chemicals and Non Prescription Drugs Branch, TGA, Department of Health and Family Services, GPO Box 9848 CANBERRA ACT 2601, for approval to import or export this product. (See also Condition No 20 of the attached Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989).

or

This product contains radioactive materials and approval to import must be obtained before importation from the Director, Australian Radiation Laboratory, Lower Plenty Road YALLAMBIE VIC 3085. Telephone: (03) 943 32211; Facsimile: (03) 943 21835.

Please note that the Chief Pharmaceutical Adviser, Department of Veterans' Affairs, would like to be provided with a copy of the approved product information for this product. The Therapeutic Goods Act does not permit the TGA to supply this now. Please consider providing a copy to:

The Chief Pharmaceutical Adviser
Department of Veterans' Affairs
PO Box 21
WODEN ACT 2606

This decision is an initial decision within the meaning of Section 60 of the Therapeutic Goods Act 1989 (the Act). This means that if your interests are affected by the decision, you may seek review of the decision 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 SECTION 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 faithfully

DELEGATE OF THE SECRETARY

Attachments:

1. Approved Product Information
2. Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989
3. Registration Form