Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Justification for a particular route of evaluation

(Schedule 10 to the Therapeutic Goods Regulations)

Please read before completing this form

This form should be completed by or for each applicant who wish to have their product or substance evaluated by an area of the TGA other than as specified in Schedule 10 to the Therapeutic Goods Regulations. This form should be directed to the Head of the evaluation area that is specified in Schedule 10, with a copy directed to the Head of the proposed evaluation area.

Please refer to the document 'Route of evaluation' for further information. Incomplete forms may be returned to the applicant.

The declaration on the last page must be signed by the applicant or by a person authorised to act on behalf of the applicant.

The address for submission of this form is:

Therapeutic Goods Administration
P O Box 100
Woden ACT 2606

Section A - Applicant details

1. Applicant's business and trading name	
2. Applicant's address	
3. Australian securities commission number	
4. Contact person for this application	
5. Contact person's Telephone number	
Contact person's Fax number	
6. Have you previously submitted an 'Enterprise Details' form for this business?	☐ Yes ☐ No
If 'Yes', give the Enterprise ID code	

If 'No', please complete an 'Enterprise Details' form (available from the TGA Publications Office) and submit it with this application.

7. Evaluation route requested for this product/substance	☐ Drug Safety and Evaluation Branch ☐ Office of Complementary Medicines ☐ OTC Medicines Section
8. Is this justification for a product or a substance?	☐ Substance (complete Sections B and D and the declaration) ☐ Product (complete Sections C and D and the declaration)

Section B - Substance details

9. Scientific name	
Is this name an Australian Approved Name?	☐ Yes ☐ No

10. Proposed or known synonyms	
11. Proposed dosage form(s)	
12. Proposed route(s) of administration	
13. Proposed therapeutic indications	
14. Proposed directions for use	

Section C – Product details

15. Product name	
16. Proposed dosage form(s)	
17. Proposed route(s) of administration	

18. Formulation details

Please provide a list of the ingredients in the product as Australian Approved Names (AANs) if possible and indicate whether each ingredient is an active ingredient or an excipient substance in the product (add a supplementary page if enough space has not been provided).

Name of ingredient	Active Yes/No	Excipient Yes/No

Name of ingredient	Active Yes/No	Excipient Yes/No

19. Proposed therapeutic indications	
20. Proposed directions for use	

Section D – Items to be attached

Please attach the information specified in the document 'Route of evaluation' including (where applicable):

- Proposed labelling
- Proposed product information

Declaration

I declare that the information given is current and correct.

The above declaration must be signed:

- in the case of a corporation by a company director or the company secretary
- in the case of other enterprises by the owner or one partner
- in the case of a consortium, or group of organisations the nominated authorised person.

Name			
Position within organisation			
Signature		Date	