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>.

Registered medicine application form

Grouped medicines*

Complementary medicines

	Page count
Clinical data	
Toxicological data	
Total	

TGA use only

Processing fee	$	Receipt number	
Evaluation fee	$	PATS ID	
Total amount received	$	Client ID	

*'Grouped medicines' means medicines that comprise a gazetted therapeutic goods group, pursuant to the Therapeutic Goods (Groups) Order No. 1 of 2001 (the Order).

This form should only be used when you wish to apply for registration of a new complementary medicine that would comprise a gazetted therapeutic goods group with a medicine already registered on the Australian Register of Therapeutic Goods (ARTG) – that is, an existing medicine.

In relation to non-export registered complementary medicines, pursuant to the Therapeutic Goods (Groups) Order No. 1 of 2001 (the Order), a new medicine and an existing medicine together comprise a gazetted therapeutic goods group if:

a. the new medicine differs from the existing medicine only in having:

   i. different indications for use; or

   ii. different directions for use; or

   iii. both different indications for use and different directions for use; and

b. the new medicine will be listed or registered in place of the existing medicine.

OR

a. the only difference between the new medicine and the existing medicine is the name given to each of them by the sponsor; and

b. the new medicine is intended to replace the existing medicine in use.

OR

a. the new medicine would, but for the Order, be taken to be separate and distinct from the existing medicine under paragraph 16(1)(a) of the *Therapeutic Goods Act 1989* only because of:

   i. a change in the quantity of an ingredient that is not an active ingredient; or

   ii. the removal or addition of an ingredient that is used only for the purpose of fragrance,

   iii. flavouring, printing ink or colouring; and

b. the new medicine is intended to replace the existing medicine in use

1.	**Sponsor's business and trading name**	Give the sponsor's business name as it appears on the Certificate of Registration for the existing product.
3.	**Sponsor's Client Identification Code**	The sponsor's client identification code is a computer-generated code allocated by the TGA. All sponsors of products registered on the ARTG will have been allocated a client identification code. If you are unsure of your code, contact the TGA eBS Help Desk.
5.	**Fees**	The appropriate application fee should accompany the application. Please note that the application fee is non-refundable. Details of fees are contained in Schedule 9 of the Therapeutic Goods Regulations 1990. Ensure cheques are made payable to 'Therapeutic Goods Administration' and are crossed and marked 'account payee only'. Foreign cheques are to be in Australian Dollars. Once the application has been accepted, the TGA will notify the applicant of the relevant evaluation fees.
6.	**Product's Registration name**	Give the name of the existing product that this new medicine proposes to replace, as it appears on the Certificate of Registration.
7.	**Product's AUST R number**	This is a unique identifying number issued by the ARTG in relation to a particular product. It appears on the Certificate of Registration of the existing product.
8.	**How does this proposed product differ from the existing product?**	Specify the type of change that you propose your product will undergo. Refer to the 'Changes' section in Part I of the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) for further information and for the relevant Codes.

Sponsor details

1. Sponsor's business and trading name	
2. Sponsor's address	
3. Sponsor's Client Identification Code	

Contact person

4. Contact person for this application	
Contact person's phone number	
Fax number	
E-mail address	

Fees

5. Application fee enclosed	A $

General details

6. Existing product's Registration name	
7. Existing product's AUST R number	

8. How does this proposed product differ from the existing product?

Code	Details

9. Existing details

Specify the details currently approved for the existing product that will differ e.g., the existing product's name.

If the proposed difference would result in changes to a label or other product material, please enclose copies of the existing and the proposed material. You should ensure that the current and the proposed material are clearly differentiated. Specify the type of material in item 12.

Refer to the 'Changes' section in Part I of the *Australian Regulatory Guidelines for Complementary Medicines* for further information.

Product details

9. Existing product's detail(s)

10. Requested details

Specify the relevant differences for the proposed product, e.g. new product name.

10. Requested detail(s)

(proposed differences)

11. Supporting data

Please specify the type and details of supporting data included with your application.

12. Product material supplied with this application

Where the proposed differences will result in changes to printed material attached to or supplied with the product or to the product information document, you should provide copies of the existing and the proposed product material (see item 9). Please ensure that the existing and the proposed product material are clearly differentiated.

Specify the type of material and attach copies to this form.

Supporting data and attachments

11. Details of supporting data submitted	Number of volumes	Number of pages
Pharmaceutical		
Preclinical		
Clinical		
Bioavailability		
Stability		
Summary		
Other (specify)		

Product material supplied with this application

12. Container label	Number of pages	
		CL
Primary pack label		**PP**
Package insert		**IN**
Product information document		**PI**
Consumer medicines information document		**CMI**
Other (Specify)		

13. Declaration

This requires a declaration to be made by the sponsor operating as an individual or partner, or where the sponsor is a corporation, a director or company secretary of that corporation or an authorised person, that the information provided in this application is true and current. Please ensure that this item is signed and dated by the appropriate person.

The sponsor may appoint a person to provide information or make decisions to the TGA on their behalf (e.g., as an agent or consultant, or the Regulatory Affairs Officer or a corporation).

The original Instrument of Appointment authorising that person to act as a duly appointed agent of the sponsor should be lodged with the ARTG as part of the *Client Details* form submitted by the sponsor. A copy of the Instrument of Appointment must be included with each variation application signed by that person.

Request for cancellation

I request that the existing product with the ARTG number _____ be cancelled from the ARTG upon the entry of this product on the ARTG.

Declaration

Applicants should note that the *Crimes Act 1914* provided penalties for false representations to the Commonwealth.

13. I apply for registration of the proposed goods described in this form, and declare that the information given is current and correct.

There are no other differences between the proposed product and the existing product (AUST R _____) other than those specified in Section 10 of this application.

Name (Please print)			
Position/Relationship to sponsor			
Signature		Date	