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 variation form

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	

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TGA Health Safety Regulation

This form should only be used when you wish to vary the particulars of complementary medicines which are already registered on the ARTG.

If the proposed changes are such as to make them 'separate and distinct goods', the changed goods will require separate registration in the ARTG. That is, you will need to submit a new registered medicine application form for the changed goods.

Goods are considered to be 'separate and distinct' if, in relation to currently registered goods, they have:

- a different formulation or composition;
- a different strength or size (disregarding pack size);
- a different dosage form;
- a different name;
- a different type of container (disregarding container size);
- different indications; or
- different directions for use.

In certain instances, 'separate and distinct' therapeutic goods can be 'grouped' in the same ARTG entry. Refer to the current 'Groups Order' and the 'Changes' section in Part I of the *Australian Regulatory Guidelines for Complementary Medicines.* If the new and existing goods may be 'grouped' a 'Registered medicine application form – grouped medicines' should be submitted.

1. Sponsor's business and trading name	Give the sponsor's business name as it appears on the Certificate of Registration.
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 processing fee and, if applicable, evaluation fee should accompany the application. Please note that the processing 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. Evaluation of this application will not proceed until the appropriate fees have been paid.
6. Product's Registration name	Give the name of your product 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.
8. Type of change	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. Processing fee enclosed	**A $**
Evaluation fee enclosed	**A $**
Total fee paid	**A $**

General details

6. Product's Registration name	
7. Product's AUST R number	

Type of change (refer to the Changes table in ARGCM)

8. Type of change

Code	Details

9. Existing details

Specify the details provided in your initial application for registration (or more recent variation) for the characteristic to be changed e.g.,

Principle manufacturer:
Aussiemedicines Pty Ltd
1 Bottle Street
Chippendale NSW 2008

If the change is to a label or other product material, please enclose copies of the original (current) and the changed (proposed) material. You should ensure that the current and the proposed material are clearly differentiated. Specify the type of material in item 13.

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

Product details

9. Existing detail(s)

10. Requested details

Specify the proposed details e.g.:

Principle manufacturer:
Southern Medicines Pty Ltd
1005 Coast Road
Atlanta Georgia 10089 USA

10. Requested detail(s)

(proposed changes)

11. Assurances

Refer to the 'Changes' section in Part I of the Australian Regulatory Guidelines for Complementary Medicines for details of the Assurances that should be provided for certain proposed changes.

12. Supporting data

Similar supporting data is required as for new registered medicine applications (e.g., where the principal manufacturer is changed from an Australian to an overseas source, certification of the standard of the overseas manufacturer is required).

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

Assurances

11. Assurances (refer to 'Changes' section in Part I of the ARGCM)

Supporting data and attachments

12. Details of supporting data submitted	**Number of volumes**	**Number of Pages**
Pharmaceutical		
Preclinical		
Clinical		
Bioavailability		
Stability		
Summary		
Other (specify)		

13. Product material supplied with this application

Where the proposed change is to printed material attached to or supplied with the product or to the product information document, you should provide copies of the current and the proposed product material (see item 9). Please ensure that the current and the proposed product material are clearly differentiated.

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

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

14. 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.

13. Product material supplied with this application

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

Declaration

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

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

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