Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

OCM

Operations	Pre-Market Assessment Section (PREMAS)
	Office of Complementary Medicines (OCM)
Procedure	Processing Applications - Administrative Procedure
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Authorised by:	
Date Issued	
Revision #	

1. Aim/Purpose/Scope

The purpose of this Standard Operating Procedure (SOP) is to provide information on the steps of processing applications within PREMAS.

2. Responsibility

The work group covered by this SOP is PREMAS.

It is the responsibility of the Administrative Assistant (APS 4) to receipt and process any new OCM applications.

Maintenance of this SOP is the responsibility of PREMAS.

3. Introduction / Background

PREMAS undertakes the evaluation of the following types of applications:

- Registration
- Registration Variation
- New Substance

4. Policy/Procedure

- A new application arrives by post/courier – REQUIRES IMMEDIATE ATTENTION IN CASE MONEY HAS BEEN RECEIVED.
- Check if application is an OCM application.
- Date stamp application.
- Immediately check to see if a cheque has been enclosed and if so:
  - Take a white copy of the covering application letter, ensuring the letter highlights:
    - Sponsor Name.
    - Find Client ID for the Sponsor in the TGA e Business Services Database and write it on the letter.
    - Type of application (eg: Registration Variation).
    - Product name.
  - Take a green copy of the cheque.

- Attach the cheque to the copy of the letter.

- Write on a 'post-it note' requesting for FSG to please advise of B/D and REC numbers once processed – Financial Services Group (FSG) will return the letter with a FSG stamp noting all the processing details including the B/D and REC numbers.

- Immediately walk the cheque down to FSG for processing.

- Fill in one of the green 'Pre-Evaluation Assessment Application Processing Checklists' – template is kept at the following location: *S:\CO\TGA\CNPD\CMS\PREMAS\PREMAS ADMIN\Pre Evaluation Assess Application Processing Checklist.doc*

- A Page Count and Data Received Proforma can be located at: *S:\CO\TGA\CNPD\CMS\PREMAS\PREMAS ADMIN\Page Count and Data Recd Proforma.doc*

- Ensure the fees paid are correct - refer to the latest 'Summary of Fees and Charges kept on the TGA Intranet: <http://www.tga.gov.au/docs/html/feesach.htm>. If not, take a note of what real fees should be and verify with Evaluation Staff. An outstanding fees letter may need to be sent or TGA may need to refund money if a higher amount has been paid.

- Invoice Request form to be completed and sent to FSG for creation, if fees paid need adjusting. A form can be obtained from the TGA Intranet: http://intranet.tga/finance/ofps-forms.htm

- If an overpayment has been made complete a Refund form and send to FSG to be actioned. A form can be located using the above link.

- Check if appropriate file exists on TRIM and order (Variation Applications only), otherwise create a new file.

- Request a new file from Records Management via email using the correct file titles.

New Substance

THERAPEUTIC ADMINISTRATION - COMPLEMENTARY MEDICINES (CM) - CM Assessment – New Substance - Application for the Evaluation of a New Complementary Medicine Substance – Sponsor name - OCM

Registration Variation

THERAPEUTIC ADMINISTRATION - COMPLEMENTARY MEDICINES (CM) - CM Assessment – Product Name - AUST R Number - Application to Vary the Registration – Sponsor Name – OCM

Registration

THERAPEUTIC ADMINISTRATION - COMPLEMENTARY MEDICINES (CM) - CM Assessment – Product Name - Application for the Registration of a New Complementary Medicine – Sponsor name - OCM

- File electronic copies of receipts and application letters/faxes in TRIM, using the record number of the file you have ordered from Records Management.

- Request data labels for any documentation submitted by the Sponsor from Records Management. The Excel spreadsheet template is located in the path below.

S:\CO\TGA\CNPD\CMS\PREMAS\PREMAS ADMIN\Template - Data Labelling for OCM

- Update PATS located at: S/CO/TGA/CNPD/CMS/PREMAS/Tracking/PATS. Make a file note of any comments for OCM application tracking (e.g. application received by {name} and has been handed to {name of evaluator} on {date}.

- Notify the sponsor that their application has been received by using the draft Notification of Receipt of Application, located at: S/CO/TGA/CNPD/CMS/SOP/Library of letters 2007 / Acknowledgement Fax. Save this letter under the electronic file in TRIM. Get the letter signed by the appropriate personnel. Fax the Notification of Receipt of Application to the Sponsor, except for Registration Variations – see evaluator first. Put a green copy of this fax or fax receipt on file.

- If an application is received from a person that is not a registered contact for that Sponsor on eBS, they will need to fill in a Client Details form. The form can be obtained from the eBS website: www.ebs.tga.gov.au – Access Form – Client Details.doc. The form will need to be emailed to ebs@tga.gov.au. Please note there is a 3 day turn around period by eBS once the form has been received.

- A copy of this SOP can be located at: *S:\CO\TGA\CNPD\CMS\standard operating procedures\PREMAS SOPs 2009\PREMAS SOPs Drafts for clearance*

5. References

- Summary of Fees and Charges kept on the TGA Intranet: <http://www.tga.gov.au/docs/html/feesach.htm>

- FSG Forms kept on the TGA Intranet: <http://intranet.tga/finance/ofps-forms.htm>