

REGISTRATION OF HOUSEHOLD REMEDIES

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To implement Administrative Order 117 s. 1992 providing for the classification of Household Remedies, the following rules on procedures for the registration of household remedies are hereby promulgated.

1.0 Application for Initial Registration of Household Remedies

1.1 The applicant shall accomplish the checklist of requirements for registration of drug products (refer to Section 3 of AO 117 s. 1992)

1.2 The application shall be processed in accordance with the procedure for registration of drugs, as follows:

1.2.1

The application will undergo pre-assessment to determine if the checklist of requirements has been completely accomplished.

1.2.2

In the first phase evaluation, the documentary requirements and the declared specifications shall be evaluated.

1.2.3

If the application passes this first phase evaluation, the application will be forwarded to the Laboratory Services Division (LSD) and LSD will notify the company to submit the samples required for assay or analysis to validate the declared formulation and specifications (MC 11 s. 1992).

1.2.4

The samples will be analyzed and the result of the analysis will be returned to the Product Services Division (PSD).

1.2.5

The PSD will undertake the second phase evaluation. If in this second phase evaluation, the PSD determines that the product falls under the household remedies classification, it shall prepare a Certificate of Product Registration (CPR) as a Household Remedy for the Director's signature. Otherwise, PSD shall indicate the proper classification of the product.

1.2.6

The validity period of the CPR and the fees will be in accordance with Section 6 of AO 67 s. 1989, viz:

Section 6

x x x

6.1 Initial Registration

x x x

Tried and Tested or Established Drug or Their Pharmaceutical or Therapeutic Innovations

Generic Drug — P500.00 per year or P2,500 for 5 years + cost of laboratory analysis

Branded Drug — P1,000.00 per year or P5,000.00 for 5 years + cost of laboratory analysis

Renewal of Registration — P300.00 per year or P1,500.00 for 5 years + cost of laboratory analysis

2. Applications for renewal registration will be processed in the same manner as application for renewal of Over-the-Counter (OTC) drug products is processed.

3. Application for re-classification may be accomplished by

3.1 filing a letter applying for a reclassification from an OTC is still effective

a. the registration of the OTC is still effective

b. that the formulation is among those classified as Household Remedies in the AO 117 s. 1992

c. or the formulation is one falling under the definition of household remedies.

3.2 The letter of application shall be accompanied by the original copy of the CPR of the OTC product.

3.3 The PSD/BFAD shall issue an amended CPR reflecting the classification of the product as Household Remedy; otherwise, if the product can not be classified as household remedy, the PSD/BFAD shall return the application for re-classification and the original CPR of the OTC product.

4. Any interested party may petition the BFAD to waive any registration requirement which may not be applicable to a specific class of household remedy.

4.1

The BFAD shall determine and decide the merits of the petition or request.

4.2

The BFAD shall then issue a Circular granting the petition to waive certain requirements or issue a letter of denial to the petitioner or requesting party.

This rule shall be effective immediately upon approval.

Adopted: 28 July 1992

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Director — CESO I

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