[BFAD MEMORANDUM CIRCULAR NO. 17 S. 1992, July 28, 1992]

REGISTRATION OF HOUSEHOLD REMEDIES

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