[BFAD MEMORANDUM CIRCULAR NO. 7, S. 1991, March 27, 1991]

CLARIFICATION OF PRESCRIBED PERIODS FOR RENEWAL REGISTRATION AND COMPLIANCE TO LETTER OF ABEYANCE

For the guidance of all concerned, the following registration policies and practices are clarified.

- 1. Application for renewal registration of drug or pharmaceutical specialty shall be filed within three (3) months <u>BEFORE</u> the expiration date of the Certificate of Product Registration (CPR).
 - 1.1 A surcharge of 50% of renewal registration fees shall be imposed upon applications for renewal registration filed WITHIN THREE (3) MONTHS <u>AFTER</u> expiration date of CPR.
 - 1.2 Application for renewal registration FILED AFTER THREE (3) MONTHS from CPR's expiration date shall be considered as initial registration.
- 2. Deficiencies listed in the Letter of Abeyance should be corrected not later than three (3) months from receipt of the Letter unless a longer period is specified in the Letter. If deficiencies are not corrected within the prescribed period, the application will be considered dropped from the active pool of application. However, within three (3) months after its classification may still be reactivated by submitting proof of correction of deficiencies not later than six (6) months after the Letter of Abeyance.
- 3. After this period, if deficiencies listed remain uncorrected, the application will be permanently cancelled.
- 4. A Memorandum of Extension (MOE) of CPR's effectivity for a period of one (1) year may be availed of while awaiting final BFAD action on its application for renewal registration, so that the product can continue to be manufactured, distributed and sold.
 - 4.1 Application for MOE should be preferably filed together with or within three (3) months from application for renewal registration.
- 5. For the determination of periods for correcting deficiencies listed in the Letter of Abeyance, the date of posting of company's name on the BFAD Bulletin Board with Product Application Routing Slip Number (RSN) shall be counted as date of receipt.
- 6. These clarifications will be applied to all new and pending application.