PHASING OUT OF THE PROCESS OF EXTENDING THE EFFECTIVITY OF CPR OR MEMORANDUM OF EXTENSION (MOE)

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The process of MOE was adopted as a temporary measure to review all registered product while compliance with AO 56 s. 1989 and AO 67 s. 1989 was initially enforced.

About four years have now elapsed from the date of effectivity and enforcement of the said administrative orders. Further, Section 18, Chapter 3, Book IV of E.O. 292 or the Revised Administrative Code provides that:

> "Where the licensee has made timely and sufficient application for the renewal of a license with reference to any activity of a continuing nature, the existing license shall not expire until the application shall have been finally determined by the agency."

Furthermore, "license" is defined in Section 2 (10) of the same code as "the whole or any part of any agency permit, certificate, passport, clearance, approval, registration, charter, membership, statutory exemption or other form of permission, or regulation, amendment, modification of a right or privilege" (italics ours).

Wherefore, the Memorandum Circular No. 18 s. 1989 is hereby revoked and the process of MOE is phased out beginning April 16, 1993.

Beginning this date.

1) application for MOE shall no longer be received for processing.

2) pending applications for MOE will be set aside and the same will be incorporated in the processes for renewal registration.

Evidence of registration of a drug product (beside the DR number on the label) shall be the certificate of product registration and the application for renewal registration duly stamped as received by BFAD with the copy of BFAD official receipt of renewal fees paid therefor.

It is, however, understood that changes of specifications such as

1. manufacturer 3. dosage form
2. active or inactive 4. dosage strength

ingredients

and other significant substantive changes in the product or affecting the product are not covered. Drug products which are undergoing changes aforecited shall be subject of an initial registration.

The application for renewal registration shall be effective only for exactly the same product already registered. Application for renewal registration will be disapproved if the registration sought to be renewed is for a product undergoing changes. In this case, the registrant may renew the old formulation while the initial registration for the amended specifications is in process.

Therefore, hereafter, application for renewal registration shall include a statement or manifestation that the

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product sought to be renewed has not undergone any change of specification.

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