Republic of the Philippines
Department of Health
BUREAU OF FOOD AND DRUGS
D.O.H. Compound
Alabang, Muntinlupa, M.M.

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BFAD CIRCULAR
No. 12 s. 1991

SUBJECT: CLARIFICATION OF NEW REGISTRATION WHEN THERE IS A CHANGE OF MANUFACTURER

SUMMARY: This circular was issued to clarify the requirements for a new registration when there is a change of manufacturer without any change in the specification covered by section 2.2. of A.O. 67 s. 1989. A conditional registration may be issued to establishment which changes manufacturer for its products to one that has better technical capabilities.

1. Section 2.2 of A.O. 67 s. 1989 (Revised Rules and Regulations on Registration of Pharmaceutical Products) provided:

"Action on registration application shall be based on the complete set of specifications of the drug product proposed to appear in the label, i.e. formulation, dosage form, strength, therapeutic indication and manufacturer. Any change in any of the above specifications will require a new registration."

2. This Circular clarifies the requirements for a new registration of a drug product with a valid registration when there is a change of manufacturer without any change in other specifications covered by Section 2.2 above.

3. When a drug establishment changes manufacturer for its product(s) to one that has better technical capabilities as evidenced by a record showing no deficiency or only minor deficiency (not substantively affecting product quality) in either GMP or its whole product lines, a conditional certificate of product registration (CPR) may be granted following the registration procedure described below:

3.1. Upon determination by BFAD that the new manufacturer meets the above criteria and upon submission of the complete requirements for product registration including the old original CPR, conditional CPR shall immediately be issued.

3.2. The CPR of the product with the old manufacturer shall automatically be cancelled with the issuance of the conditional CPR with the new manufacturer. The products produced by the old manufacturer before the new conditional CPR is issued will be allowed in the market until expiration date of the product.

3.3. The conditional CPR shall be effective for a period of one (1) year subject to the results of the BFAD Laboratory Tests and Stability Studies on the product of the new manufacturer. Unsatisfactory results will mean the immediate cancellation of the conditional CPR.

If the product passes satisfactorily the BFAD Laboratory Tests and stability studies, a regular certificate of product registration good for five (5) years shall be issued.

4. Change to manufacturer not meeting the above criteria defined in paragraph 3 shall continue to be eligible for Special Lane.

This Circular takes effect immediately.

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