[BFAD ADMINISTRATIVE ORDER NO. 54, S. 1999, December 22, 1999]

CHANGE OF MANUFACTURERS OF DRUG PRODUCTS IN COMPLIANCE WITH THE CGMP REQUIREMENTS

Pursuant to BFAD Circular No. 3, Series of 1998 and other issuances mandating manufacturing facilities to strictly comply with CGMP Requirements beginning January 1, 2000 and in order to provide transitory measures for drug establishments whose products will be affected thereby, the following rules and regulations are promulgated for the information, guidance and compliance of all concerned.

1. Issuances of a new Certificate of Product Registration (CPR) is required if there is a change in the manufacturer as contemplated above and provided that the following conditions are met:

1.1 The LTO of the current manufacturer shall be cancelled due to non-compliance with the A.O. on CGMP.

1.2 The new manufacturer has already been certified as CGMP Compliant.

1.3 The drug product is validly registered with the BFAD.

1.4 There shall be no change in the formulation, and manufacturing process of the product.

2. Application for CPR shall be supported by the following documents:

2.1 Copy of the LTO of applicant and the new manufacturer

2.2 Agreement between the applicant and the new manufacturer for product accountability.

2.3 Complete set of documents in accordance with the 1997 Guidelines for Registration of Pharmaceutical Products reflecting the name of the new manufacturer.

2.4 Process validation data such as Certificate of Analysis of product as manufactured by the new manufacturer for three production batches.

2.5 Multi-point dissolution profile done on the product, when applicable, as produced by the current and the new manufacturer using compendial or application requirements.

2.6 Transitional labeling materials reflecting the complete name and address of the new manufacturer.

A CPR valid for six (6) months shall be issued for applications that could not immediately supported by document Nos. 2.4 and 2.5 as stated above, on the