



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

Filinvest Corporate City
Alabang, Muntinlupa City



June 08, 2000

BFAD CIRCULAR
No. 03-A s. 2000

**SUBJECT: Amendment to FDA Circular No. 2 s. of 1982
on the Importation of Semi-Synthetic Antibiotics**

Pursuant to Executive Order No. 776, dated February 24, 1982 and by way of amendment to FDA Circular No. 2 dated April 30, 1982, the following rules and procedure for the importation of antibiotics are hereby adopted:

A. Commodities Covered

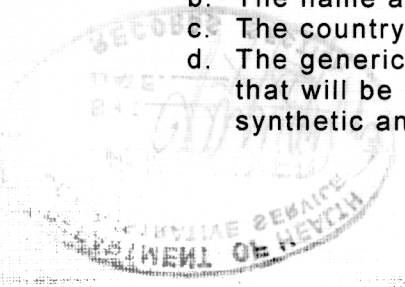
1. Semi-synthetic antibiotics produced in the Philippines shall refer to all forms and salts of ampicillin, amoxycillin and cloxacillin.
2. In accordance with Executive Order No. 776, importations of semi-synthetic antibiotics shall be allowed only for quantities and types that cannot be produced in the Philippines.

B. Qualification of Importers

1. The importer should be a drug manufacturer or trader manufacturing or producing antibiotics for its own account duly registered as such with the Bureau of Food and Drugs (BFAD);
2. The importation of semi-synthetic antibiotics shall be used exclusively by the importer for the manufacture of its own brand of semi-synthetic antibiotics in dosage/strength forms duly registered with the BFAD.

C. Authorization To Import

1. All application for the importation of antibiotics shall be filed with BFAD, and shall contain the following data:
 - a. The name and address of the Agent Bank
 - b. The name and address of the Importer
 - c. The country of origin of the antibiotics
 - d. The generic, chemical, brand/trade name of the finished product that will be manufactured or produced using the imported semi-synthetic antibiotics




- e. The form of the antibiotics
 - f. The quantity of the antibiotics
 - g. The pro-forma invoices covering the products to be imported indicating the specifications, prices and delivery dates
2. The Director, BFAD, by Authority of the Secretary of Health, shall issue a Certificate of Authority to Import Semi-Synthetic antibiotics and other antibiotics;
 3. The Authority to Import shall be valid for ninety (90) days from date thereof for the purpose of importation and shall be used only once;
 4. Each Authority to Import should refer to one antibiotic either as finished product or raw materials;
 5. The original copy of the Certificate of Authority to Import shall be submitted to Agent Bank, who shall then furnish BFAD, thru CICO of the Central Bank, with copies of the Letter of Credit/Acceptances issued under this specific authority and the corresponding release certificate issued therefor.
 6. The Bureau of Customs will allow the release of such importation only upon presentation of the Authority to Import together with all the other requirements in force including the Certificate of Analysis of every batch of raw material and/or finished products.

D. Submission of Production Records

1. Each and every importer is required to submit to BFAD complete records of production and usage report of the imported raw materials within ninety (90) days from the date of usage of imported materials. Any diversion or unauthorized use of the imported raw materials or failure to submit the production record and usage report as required shall be a ground to deny application for further authorization to import without prejudice to the filing of appropriate legal sanctions as shall be warranted.


WILLIAM D. TORRES, Ph.D.
Director

Approved:


ALBERTO G. ROMUALDEZ, JR., M.D.
Secretary of Health

IMG/ayeth
<issnce*bc-antibiotics>