

[BFAD CIRCULAR NO. 03-A, S. 2000, June 08, 2000]

AMENDMENT TO FDA CIRCULAR NO. 2, S. OF 1992 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 applications 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