[BFAD ADMINISTRATIVE ORDER NO. 23-C, S. 2000, March 03, 2000]

POLICIES AND GUIDELINES ON OVER THE COUNTER (OTC) DRUG PRODUCTS

Pursuant to Sec. 26 of Republic Act No. 3720, as amended, the following policies and guidelines on over the counter (OTC) drug products are hereby promulgated to govern the registration and classification of drugs and medicines in the market.

SECTION 1. Definition — Over the Counter (OTC) drugs are drug products that can be dispensed even without the written order or prescription of a licensed physician or dentist for human use, for the symptomatic relief of minor or self-limiting ailments. These drug products shall be sold only in BFAD licensed drug outlets under the direct supervision of a registered and licensed pharmacist.

SECTION 2. Criteria for Classification as OTC Drug —

A. For a drug product to be classified as OTC, it shall meet the following general criteria:

1. The drug product is time-tested and has undergone thorough investigation and extensive clinical use;

2. The drug product is recognized to contain active ingredient(s) with proven safety and efficacy (wide margin of safety and high therapeutic index) even without professional supervision as proven by adverse drug reaction (ADR) monitoring; and

3. The drug product is neither with bioequivalence problem (List B) nor classified as prohibited or regulated by the Dangerous Drugs Board (List A) or as internationally controlled drug product by the International Narcotics Control Board (INCB).

B. To determine the drug product's conformity with the foregoing general criteria, the manufacturer or importer as the case may be, shall submit for evaluation the following documents showing/proving that:

1. Under recommended conditions of use, the product is safe and effective;