Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
M a n i l a
SAN LAZARO COMPOUND
RIZAL AVENUE, STA. CRUZ
MANILA, PHILIPPINES

9 March 2000

ADMINISTRATIVE ORDER
No. 23-C s. 2000

SUBJECT: **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 condition of use, the product is safe and effective;

2. The concentration(s) of the active ingredient(s) have been found to be clinically safe and effective and do(es) not exceed the maximum limit approved by the Secretary of Health for symptomatic relief of minor or self-limiting ailments;

3. The worldwide incidence of reported adverse drug reactions (ADRs) and interactions of the drug is low and clinically insignificant;

4. The number of years the drug product has been released in the international market and the sale of the originally registered strength and form is at least twenty (20) years and in the Philippine market for at least ten (10) years; and

5. The drug product, if imported, is classified and marketed as an OTC on non-prescription drug in the country of origin and marketed in at least two (2) of the following countries: Canada, United Kingdom, United Kingdom, United States of America, Japan, Australia, and Sweden.

Section 3. Procedure for the Registration of OTC Drug Products

1. The manufacturer or trader or importer shall file the application with BFAD for the classification of the drug product as OTC. The Director shall refer the application to the Technical Advisory Committee of BFAD for evaluation and corresponding recommendation;

2. Upon the approval of the classification of the drug product as OTC by the BFAD Director, the applicant shall then proceed to comply with the current standards and requirements for reclassification of pharmaceutical products as OTC;

3. A Certificate of Product Registration as an OTC drug product shall be issued after the determination of the product's compliance with the standards and requirements for registration; and

4. Pharmaceutically equivalent drug products shall be similarly classified as OTC or prescription drug, as the case may be.

Section 4. Authority to Revoke/Withdraw the Approval of the Classification as OTC Drug Product

The Secretary of Health, through the Director of the Bureau of Food and Drugs, shall retain the authority to recall and withdraw the approval of the classification as OTC of a drug product in the event of any documented and verified adverse reactions endangering public health and safety and if it has been reclassified as an internationally controlled drug product by the INCB after due notice to the registered drug manufacturer, trader or importer.

Section 5. Repealing Clause

All Administrative Orders, Rules and Regulations and other Administrative issuances or parts thereof, inconsistent with the provisions of the Administrative Order are hereby repealed and modified accordingly.

Section 6. Effectivity

This Order shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation.

(Sgd) ALBERTO G. ROMUALDEZ,JR.,MD
Secretary of Health