



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

June 15, 1979

ADMINISTRATIVE ORDER
NO. 38 s. 1979

SUBJECT: RESTRICTION ON THE USE OF SEVERAL BRAND NAMES FOR A FORMULATION OF A DRUG OR PHARMACEUTICAL SPECIALTY.

The practice of drug manufacturers and importers/licensee of allowing their distributors to market and promote a drug or pharmaceutical specialty of same formulation and specification under several brand names serves only to confuse the practicing physicians and the consuming public. Likewise, it gives a false impression of the number of drugs or pharmaceutical specialties in the country.

In order to check and stop the proliferation of several brand names for a specific formulation and Specification of a manufacturer, exclusive distributor or licensee, this Regulation is hereby promulgated;

1. A drug or pharmaceutical specialty shall be registered with this Office and henceforth marketed only under its generic name, or brand name of the manufacturer, exclusive distributor or licensee.
2. The brand name of a formula owner, the product of which is produced by contract manufacture, shall be accepted for registration only if it can be established that the product is definitely different from the product of the manufacturer, if any, otherwise item 1 applies. Among other things, contract or agreement, protocol of production and technical specification will have to be submitted.
3. The registration of drugs and pharmaceutical specialties produced by a manufacturer or imported by an exclusive distributor/licensee and distributed by different person under different names shall be allowed to continue until the expiration of the validity of registration. Henceforth, renewal of registration shall only be allowed under condition of item 1.
4. Any manufacturer, importer or wholesaler who permit registration of a drug or pharmaceutical specialty under different names by the distributor is subject to Section 19 (a) of RA 3720 for misbranding section 11 (a) of the same Act and PD 280 for violation of the rules and regulations.

This Regulation shall take effect immediately upon approval.

ARSENIO M. REGALA, Ph.D.
Administrator