



Republic of the Philippines
Ministry of Health
BUREAU OF FOOD AND DRUGS
Manila

November 17, 1986

BFAD REGULATION

No. 2 s. 1986

SUBJECT : ASSIGNMENT OF BRAND NAME AND/OR GENERIC NAMES FOR A FORMULATION OF A DRUG OR PHARMACEUTICAL SPECIALTY

SUMMARY: This Regulation clarifies and updates the restriction on the use of several brand names for a given formulation and repeals A.O. 42 s. 1979 and all other A.O. inconsistent to this Regulation.

For the purpose of clarifying and updating the restriction on the use of several brand and/or generic names for a formulation of a drug or pharmaceutical specialty brought about by Administrative Orders No. 131 s. 1970, No. 38 s 1979 and No. 42 s 1979, the following regulations are hereby promulgated, for the information and guidance of all concerned:

1. All drugs and/or pharmaceutical specialties, whether imported or locally manufactured, shall be registered with the Bureau of Food and drugs (BFAD) under their generic and/or brand name prior to local marketing.
2. For a locally manufactured drug of pharmaceutical specialty, the owner of the product which is either manufacturer, drug department, distributor or his duly authorized representative shall register the product, should the product be imported, the importer and/or distributor or his duly authorized representative shall register his product.
3. A drug manufacturer, toll/contract manufacturer, distributor, drug department or licensee can use a brand name and/or generic name for a given formulation of a drug or pharmaceutical specialty with a single active ingredient; Provided however, that brand name will not have an identical nor similar name with those previously and/or already registered with this Office.
4. No imported drug or pharmaceutical specialty, though patented and/or registered in other countries, will be registered if there exists an identical or similar brand name already registered with BFAD.
5. Every manufacturer, drug department/distributor, toll/contract manufacturer can use a brand name and/or generic name for every formulation of a drug or pharmaceutical specialty with a single active ingredient; Provided, it will have different color and distinguishing mark or logo for every drug department or distributor; and provided further, that subject product must comply with the fixed minimum and maximum upper-level amount of active ingredients based n their therapeutic effects to be determined by BFAD.
6. The brand name and formulation of any drug or pharmaceutical specialty previously registered by the licensee for the foreign manufacturer shall, upon termination of the contract of manufacturing agreement between both parties, be allowed to be carried by

the licensee for the purpose of manufacturing and marketing it locally; Provided, however, that this arrangement is explicitly provided for in the contract.

7. Every brand name of a drug or pharmaceutical specialty shall be submitted for name clearance to BFAD prior to registration. The purpose of the name clearance is to prevent similarity of the brand name with other previously registered drug products.
8. The general procedures for clearing brand names are:
 - 8.1. brand name must not be confusing in speech, in rhyme or in writing with other registered brand names.
 - 8.2. brand name must not be confusingly similar nor identical with the first syllables unless the middle syllables create distinctive appearance and sounds.
 - 8.3. brand name must be different either in prefix, middle or suffix syllables if applied to the different generic class of drugs or where the drugs have different indications to prevent confusion.
 - 8.4. brand name must not be identical nor similar to INN (International Non-proprietary Names).
 - 8.4.1. by changing or dropping a single letter or syllables from the INN
 - 8.4.2. by including INN stems
 - 8.4.3. by combining with INN elements for multicomponents products:
 - 8.5. brand name must not, in any way, conflict with the established guidelines as outlined in MOH Administrative Order No. 76 dated January 24, 1984.

This regulations repeals Administrative Order No. 42 s. 1979 and all other Administrative Issuances inconsistent hereof and shall take effect upon its approval.

(Sgd) CATALINA C. SANCHEZ
Director

APPROVED:

(Sgd) ALFREDO R.A. BENGZON, M.D.
Ministry of Health