

GUIDELINES FOR THE EVALUATION OF BRAND NAMES FOR PRODUCTS TO BE REGISTERED WITH THE BUREAU OF FOOD AND DRUGS

BUREAU CIRCULAR NO. 21, S. 1999, October 27, 1999

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For purposes of clarifying and updating the requirements and procedures in the evaluation of brand names for foods, drugs, medical devices, diagnostic reagents, cosmetics, and household hazardous products to be registered with the Bureau of Food and Drugs, the following guidelines are hereby issued, for the information and guidance of all concerned.

A. General Requirements:

1. Every brand name of a food, drug, medical device, diagnostic reagent, cosmetics and household hazardous product to be registered with the Bureau of Food and Drugs shall be subject to evaluation and approval as part of the registration process. This is to prevent similarity of the brand name with other previously registered product.
2. A brand name of imported product, though patented and/or registered in other countries, will not be allowed if there exists an identical or similar brand name already registered with BFAD.
3. The following names shall not be allowed:
 - 3.1 Deceptive brand name;
 - 3.2 Deceptively descriptive brand names such as Best, Outstanding, Most Effective, Wonder Drug, and the like;
 - 3.3 Geographically descriptive names which gives false impressions to the country of origin of the product such as Canadian Food Supplement, European Herbal Drug, etc.
 - 3.4 A brand name which is identical or similar to another brand name that is registered or previously cleared with the BFAD;
 - 3.5 A brand name which would confuse the public and unwary consumers and deceive them into believing that the product bearing one label are similar or produced by the same manufacturer as those carrying the other label;

B. Specific Requirements for Pharmaceutical Products:

1. For every manufacturer, trader, and distributor/importer/exporter, only one brand name shall be allowed for a given pharmaceutical formulation registered in their name. Differences in a pharmaceutical formulation shall be based only in active ingredient(s). However, products containing the same active ingredient(s) but used for different therapeutic indication(s) shall be allowed to carry another brand name.
2. A brand name that has been used for a given formulation must not be used for a new formulation with a different active ingredient or additional active ingredient;

3. The following guidelines shall be followed in the evaluation and approval of brand names for pharmaceutical products:

3.1 Brand name must not be confusing in speech, in rhyme or in writing with other registered or previously cleared brand names;

3.2 Brand name must not be confusingly similar or identical with the first syllables of a registered or previously cleared name, unless the middle syllables created a distinctive appearance or sounds;

3.3. Brand name must be different either in prefix, middle or suffice syllables if applied to the different generic class of drug or where the drugs have different indications to prevent confusion;

3.4 Brand name must not be identical nor similar to INN (International Non-Proprietary Names)

3.4.1 By changing or dropping a single letter or syllable from the INN

Ex. Paracetam — Paracetamol is INN

3.4.2 By including INN stems (see list of INN Stem in Annex A)

Ex. Laracillin — cillin is an INN stem

3.4.3 By combining with INN elements for multi-component products

Ex. “Sulfaprim” for product containing Sulfadoxine and Trimethoprim

C. Procedure for Approval of Brand Names

1. Prior to the submission of application for registration of branded products, the applicant company shall check the proposed brand name against the list of BFAD registered and approved brand names, which shall be posted in a convenient place within the BFAD, for any similarities. It shall be incumbent upon the applicant company to ensure that their proposed brand name is not identical or similar to any of the listed brand names

2. All applications for registration of branded product shall be submitted and accepted in accordance with existing rules for product registration

3. The PSD evaluator shall consider the acceptability of the proposed brand name in accordance with the requirements stated in Sections A and B of this Circular, as part of the process of evaluation of product for registration. Approval of the brand name shall be based on its compliance with the above stated requirements.

4. Unacceptable brand name shall be ground for the non-approval/denial of the application for registration of the product.

D. Special Condition to be Printed On the CPR of Branded Products

All Certificates of Product Registration (CPR) issued henceforth, shall carry the following Special Condition:

“Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by BFAD, that Registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agree and affirm to indemnify and/or hold BFAD free and harmless against any and all third-party claims on the infringement of patent, trademark or industrial design rights arising from the registration of the product(s) listed on the other side hereof.”

For the information and immediate compliance of all concerned.

Adopted: 27 Oct. 1999

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