Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila

SENTRONG SIGLA
Health ang unat

21 June 2005

ADMINISTRATIVE ORDER
NO. 2005-0016

SUBJECT: **General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drugs**

I. RATIONALE

It is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them (Section 15, Article II, 1987 Constitution).

To achieve such objective, the State was mandated to (a) adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost (Section 11, Article XIII, 1987 Constitution); and (b) establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems (Section 12, Article XIII, 1987 Constitution).

In view thereof, Republic Act No. 3720, as amended by Executive Order No. 175, series of 1987, otherwise known as the *"Food, Drugs and Devices and Cosmetics Act"*, was enacted to establish an effective system in the registration, monitoring and regulation of food, cosmetics, drugs, devices, and household hazardous substances.

In the system for the registration of products, and as part of the registration process, the Bureau of Food and Drugs (BFAD) evaluates and approves the brand names of products applied for registration to implement the misbranding provisions of R.A. No. 3720, as amended, pursuant to Administrative Order No. 76 s. 1984 *(Subject: Guidelines to be observed by FDA (BFAD) in Clearance of Name Relative to Food, Drugs and Cosmetics)* and in relation to the pertinent provisions of R.A. No. 6675, otherwise known as the *Generics Act of 1988*, to promote the use of generic pharmaceutical products.

Nevertheless, in the registration of products with BFAD, issues concerning intellectual property rights over brand names have been raised that

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have effectively impeded the achievement of the abovementioned constitutional mandate and objectives.

Meanwhile, pursuant to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, issues pertaining to intellectual property rights, particularly patent rights, trademarks, trade names, copyrights, and unfair competition, are properly lodged with either the Intellectual Property Office (IPO) or a court of law with competent jurisdiction on the subject matter.

II. PURPOSE AND OBJECTIVE

The purpose of this Order is to establish the general policies and guidelines governing brand names of products for registration with BFAD and the promotion of generic/unbranded pharmaceutical products, in recognition of the respective mandate, authority, and jurisdiction of this Department, through BFAD, the IPO, and the court of law with competent jurisdiction over intellectual property rights disputes.

This Department acknowledges that it is not the gatekeeper in the promotion and regulation of brand names which are often times being used as marketing tools, without any connection or relation whatsoever to the safety, efficacy and quality of the products. In issuing this Order, this Department, through BFAD, hereby reiterates and consistently adopts its mandate and responsibility to only ensure the safety, efficacy and good quality of products applied for registration.

III. SCOPE AND COVERAGE

This Order shall cover all food, cosmetics, drugs, devices and household hazardous substances applying either for initial registration or change in brand name or inclusion of brand name for registered generic/unbranded pharmaceutical products with BFAD.

IV. DEFINITION OF TERMS

1. ***"Brand Name"*** is the name appropriated by the manufacturer, trader or importer to distinguish its product in the market.

2. ***"Certificate of Product Registration (CPR)"*** is the certificate being issued to a licensed manufacturer/trader/importer/distributor for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.

3. ***"Certificate of Product Listing (CPL)"*** is the certificate being issued to a licensed manufacturer/trader/importer/distributor for the distribution and/or sale of a cosmetic specialty qualified for listing (without pre-market approval) with the BFAD after its evaluation for safety, efficacy and quality.

4. ***"Generic Name or Generic Terminology"*** is the identification of drugs and medicines by their scientifically and internationally recognize active ingredients or by their official generic name as determined by BFAD.

5. ***"Product Classification"*** means the separate and distinct classification between and among food, cosmetic, drug, veterinary product, device, diagnostic reagents, and household hazardous substance. This means that the classification for food, etc. is separate and distinct from the classification for cosmetic and the others.

V. GENERAL GUIDELINES

Pursuant to the abovementioned purpose and objective, and to implement the misbranding provisions of R.A. No. 3720, as amended, this Department, through BFAD, hereby adopts the following general guidelines:

Section 1. As a general rule, any name may be accepted as the brand name of the product under application for Certificate of Product Registration (CPR)/Certificate of Product Listing (CPL).

Nevertheless, pursuant to the *Generics Act of 1988*, the Department highly encourages and supports the non-utilization of brand names and the use and promotion of generic/unbranded names for pharmaceutical products under registration.

Section 2. Only the following brand names shall not be allowed:

(a) Names that are identical to those already registered with the BFAD in the same product classification; and

(b) Names that are offensive, obscene, scandalous or otherwise contrary to public morals and policy.

Section 3. The existing system for brand name clearances is hereby abolished. In its place, the evaluation and acceptance of the proposed brand name(s) shall be done simultaneously with the processing of the application for CPR/CPL.

In the event that there be a change in the brand name of a registered product, or inclusion of a brand name for a registered generic/unbranded pharmaceutical product, the evaluation and acceptance of the proposed brand name should be performed within thirty (30) days upon submission, otherwise it shall be deemed as accepted upon the expiration of such period.

Section 4. The acceptance by BFAD of the proposed brand name shall not be interpreted or construed as an approval, endorsement or representation that the applicant has the right or privilege to the use of the brand name so submitted.

Section 5. The applicant shall execute an affidavit of undertaking (a) to change the brand name so submitted should the proper authority decides with finality that he/she/it has no right to appropriate and utilize said brand name; and (b) to acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with BFAD. The affidavit of undertaking shall be incorporated in or attached to the application for CPR/CPL.

VI. DISPUTES

Section 1. In the event that any interested party notifies BFAD in writing of any alleged prior or existing intellectual property right over the brand name of the product pending registration, BFAD shall immediately respond to said party, in writing, that intellectual property matters are beyond the legal mandate of BFAD and that their proper recourse should be from the IPO or the appropriate courts of competent jurisdiction.

Section 2. Under no circumstance shall the filing of any such notification be the reason or cause to suspend, delay, or otherwise adversely affect the processing of the application for, and the issuance of the CPR/CPL until and unless BFAD is restrained or enjoined by the proper authorities from doing so. In this instance, "proper authority" shall only pertain to the IPO or courts of law with competent jurisdiction over the said subject matter.

VII. SEVERABILITY CLAUSE

If any part, term or provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

VIII. TRANSITORY AND REPEALING CLAUSE

This Order shall likewise apply to previous applications for brand name clearances which remain pending before the issuance hereof. Meanwhile, Administrative Order No. 76, series of 1984, Bureau Circular No. 21, series of 1999, Bureau Circular No. 08, series of 2003, and all other administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/or revoked accordingly.

IX. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in a newspaper of general circulation.

FRANCISCO T. DUQUE III, M.D., MSc.
Secretary of Health