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August 10, 2006

ADMINISTRATIVE ORDER
NO. 2006 - 0021

Subject: **Supplemental Guidelines to Administrative Order (AO) 67 s. 1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 in evaluating New Drug Applications**

I. RATIONALE

Article XIII, Section 11 of the 1987 Constitution provides that the State shall 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.

In consonance with the above Constitutional provision, the Government fully agrees that affordable medicines and equitable access to health care are fundamental human rights and protecting these rights is the Government's moral obligation to its people. It is saddening to note however, which the Department of Health recognizes, that while steps have been taken to bring down the costs of medicines such as the passage of the Generics Act of 1988 and the parallel importation of low-cost essential drugs, drug prices are still artificially high and unreachable for most of the Filipino people. Thus, one of President Gloria Macapagal-Arroyo's 10-Point Agenda and her repeated calls in her State of the Nation Address is to reduce the cost of medicine by at least fifty-percent (50%).

Accordingly and to facilitate access to affordable medicines by fostering an environment that promotes competition, streamlining drug registration procedures of the Bureau of Food and Drugs is, thus, imperative.

Hence, to protect public health by creating an environment that will lower the costs of medicines through greater competition among drug companies, provide the government with better policy tools to significantly influence the supply and demand of medicines and pursuant to Section 26(a) of Republic Act No. 3720 as amended, known as the Foods, Drugs, and Devices and Cosmetics Act, the following are introduced in addition to the provisions of AO 67 s. 1987 and BC 5 s. 1997 particularly in the registration of new pharmaceutical products for the information, guidance and compliance of all concerned.

II. Objectives

1. To provide supplemental guidelines that would reinforce the implementation of AO 67 s. 1989 and BC 5 s. 1997;

2. To ensure adaptation mechanisms to emerging issues not otherwise covered by current policy regimes; and

3. To provide guidance in drug evaluation of new drugs as defined in RA 3720, as amended by Executive Order No. 175 dated May 22, 1987.

III. General Guidelines

1. The Bureau of Food and Drugs shall be authorized to adopt measures and methods that would address drug evaluation issues not otherwise addressed by previous administrative and regulatory constraints to ensure adaptive efficiency of rules as a consequence of new technologies, doctrines, and harmonization of standards in the evaluation of new drugs that are intended to enter the Philippine market.

2. Drug registration application of pharmaceutical products that are already in foreign markets shall be evaluated using data submitted to the Drug Regulatory Agency of the country it is marketed and other post market data that would supplement or serve as alternative measures to existing regulatory requirements, without undermining domestic standards on safety, efficacy and quality of drug products.

IV. Specific Guidelines

A. Informational Requirements under New Drug Application (NDA) Summary should include the following:

a. proposed text of labeling of the pharmaceutical product with appropriate information in the summary and technical sections that support the addition of any statement in the labeling;

b. a statement indicating the pharmacologic class of a drug and scientific justification of the drug, its clinical indications and therapeutic benefits;

c. brief description of its marketing history which shall also include:
   - the countries where the drug has been marketed or withdrawn whether for safety and efficacy reasons, and
   - the countries where applications are pending, if any.

d. summary of the chemistry, manufacturing and control section of the application;

e. summary of human pharmacodynamics and pharmacokinetics and bioavailability;

f. summary of microbiology (for anti-infectives only);

g. summary of clinical data section of the application;

h. a concluding discussion that states the benefit and risk considerations related to the drug;

i. discussions of the proposed post marketing surveillance study/ Monitored Release Study after approval of the drug; and

j. information from an Investigator's Brochure shall be subject to BFAD audit and verification.

B. Treatment on the number of subjects under Clinical Investigation Data

a. The number of subjects under Clinical Investigation Data as provided for in BC 5 s. 1997 shall be treated as mere guide for purposes of ensuring statistical robustness of findings on safety, efficacy, and quality. Albeit, on specific circumstances where such constraints can not be adequately sufficed and for practical purposes, the BFAD shall require the applicant the following as proxy indicators/measures, *to wit*.

i. a circumstance unique to the product subject for registration can be demonstrated;

ii. an applicant / sponsor adopts an acceptable approach which had not been previously been considered by BFAD;

iii. acceptable alternative studies have been or must be conducted to satisfy the criteria of quality, safety and efficacy;

iv. Post Marketing Surveillance must be conducted;

v. submission of quarterly report of the results of the monitoring of said results of the Post Market Surveillance; and

vi. such other indicators/measures as the BFAD may deem necessary and reasonable to ensure safety, quality and efficacy.

b. Proxy indicators/measures that would be used as supplementary and/or alternative measure for drug evaluation must be deliberated by the Advisory Committee for BFAD (ACB), must be concurred by the Product Services Division (PSD), and must be subject to the approval of the BFAD Director.

V. Repealing Clause

The particular provisions of Administrative Order (AO) 67 s. 1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 are hereby modified accordingly.

VI. Separability

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.

VII. Effectivity

This Order shall take effect immediately upon publication.

FRANCISCO T. DUQUE, III, MD, MSc
Secretary