Republic of the Philippines
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

13 May 2010

ADMINISTRATIVE ORDER
No. 2010 - 0012

SUBJECT: **Policy Requiring the Temporary Suspension of Acceptance by the Food and Drug Administration of Initial Applications for Drug Product Registration and Criteria for Refusal of Applications for Renewal of Drug Products with more than One Hundred (100) Registered Pharmaceutical Formulations**

I. RATIONALE

It is the policy of the State to 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 response to the above policy, Republic Act No. 6675 or the "Act to Promote, Require and Ensure the Production of Adequate Supply, Distribution, Use and Acceptance of Drugs and Medicines Identified by their Generic Names", was ratified. The passage of the aforementioned law paved the way for the establishment and implementation of the National Drug Policy with the end in view of addressing, among others, the public demand for essential health services and drug supply in the Philippines.

Accordingly, one area identified requiring attention is the management of drug supply. Striking a balance between those drugs that are already flooding the market, as against those essential drugs that are still needed by the people must be pursued.

Recent laws passed in the area of making essential goods, health and other social services available to the people include Republic Act No. 9502, otherwise known as the Universally Accessible Cheaper & Quality Medicines Act of 2008 and Republic Act No. 9711, otherwise known as the Food & Drug Administration Act of 2009. These laws open the entry of more competitive quality drugs into the country. This scenario may result in an unmanageable increase in the number of pharmaceutical products for registration.

Thus, to be able to provide a more efficient and effective service on matters of registration of essential drug products and to ensure that only those drug products consistently complying with the standards and criteria for registration are made available on the market, a policy of limiting the further registration of drugs that are already flooding the market becomes imperative.

II. SCOPE

This Order shall apply to the initial registration of a drug product, more than one hundred (100) of which are already registered by the Food and Drug Administration (FDA) formerly BFAD in the Philippines or the renewal of registration of a drug product that is not being marketed or has failed the current Good Manufacturing Practices (cGMP) standards .

III. DIRECTIVE AND GUIDELINES

Consistent with the above declaration, the ensuing guidelines shall be pursued:

1. The FDA, from the effectivity of this Order, shall immediately refrain from accepting initial applications for the registration of a drug product that already has *more than one hundred similar drug products currently registered with the FDA regardless* of whether these are imported or locally produced.

2. The following criteria shall be used to refuse application for renewal of registration of drug products:

    a. Any registered drug product which was not marketed for an uninterrupted period of two (2) years prior to the application for renewal of registration without legitimate reason/s.

    b. Non-compliance with the current Good Manufacturing Practices (cGMP) at the last inspection by the FDA prior to the application for renewal of registration.

3. For this purpose the FDA is hereby required, within fifteen (15) working days from effectivity of this Order to post in a conspicuous place within the premises of the Office and to publish in its website the list of drugs that have c urrently more than 100 preparations/brands registered with FDA. FDA shall periodically update the list for the guidance of everyone concerned.

IV. SEPARABILITY 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.

V. REPEALING CLAUSE

All administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/or revoked accordingly.

VI. EFFECTIVITY CLAUSE

It is therefore, ordered that the acceptance of applications for initial registration and renewal of all aforecited pharmaceutical products be temporarily suspended, effective immediately, until further notice.

This Order shall take effect immediately.

ESPERANZA I. CABRAL, MD
Secretary of Health