[DOH ADMINISTRATIVE ORDER NO. 2005-0031, December 07, 2005]

GUIDELINES AND PROCEDURE FOR THE ISSUANCE OF THE PRINCIPAL CERTIFICATE OF PRODUCT REGISTRATION AND THE LISTING OF IDENTICAL DRUG PRODUCTS BASED ON THE IDENTITY OF MANUFACTURER AND PHARMACEUTICAL FORMULATION

I
Rationale

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

Accordingly, 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, licensing, monitoring, and regulation of drugs or pharmaceutical products, among others.

In the registration of drugs or pharmaceutical products, however, the Bureau of Food and Drugs (BFAD) observes that registered owners, such as toll manufacturers, traders and/or importers, of pharmaceutical formulations with previously issued Certificates of Product Registrations ("CPRs", for brevity) grant to third persons the license to export, import, distribute, sell or market these same formulations but which would thereafter be covered by separate CPRs.

Thus, regardless of the identity of source of the same pharmaceutical formulation, the BFAD individually processes the corresponding CPR applications, thereby requiring multiple evaluation of separate CPR applications for the same pharmaceutical formulation with an identical manufacturer of the finished product.

Consequently, this individual processing (a) unnecessarily duplicates evaluation of CPR applications, thereby increasing BFADs workload; and (b) channels evaluation time and effort away from CPR applications for new pharmaceutical formulations to CPR applications for existing formulations already evaluated and recognized by BFAD.

Therefore, allowing the listing of a pharmaceutical product based on the identity of manufacturer and of the pharmaceutical formulation, which is already covered by a prior valid CPR, will expedite their registration process and permit BFAD to direct more time and effort to new product registrations while ensuring continued availability of pharmaceutical products at lower prices.

II
Purpose and Objective

The purpose of this Order is to: (a) simplify and expedite the registration of pharmaceutical products based on the identity of the manufacturer and of the same pharmaceutical formulation by linking them, if applicable, to the Principal CPR; (b) ascertain and establish responsibility in the manufacture, exportation, importation, distribution, sale and/ or offering for sale of pharmaceutical products based on identity of the manufacturer and of the same pharmaceutical formulation; and (c) assist BFAD in conducting post-market surveillance of the pharmaceutical products.

III
Definition of Terms

1. "Certificate of Product Registration (CPR)" is the certificate issued by BFAD for the purpose of marketing or free distribution of a product after evaluation of its safety, efficacy and quality.

2. "Principal CPR" means the first, or prior, existing and valid CPR of a particular pharmaceutical product with a particular pharmaceutical formulation issued to the owner/ holder thereof who/which grants to third persons the authority or license to export, import, distribute, market and/or sell the same pharmaceutical formulation.

3. "Principal Product" means the pharmaceutical product covered by a Principal CPR.

4. "Principal Formulation" means the pharmaceutical formulation of the Principal Product.

5. "Identical Drug Product" means the pharmaceutical product that is identical in terms of the manufacturer of the finished product and identical in terms of the pharmaceutical formulation vis-a-vis the Principal Product.

6. "Identical Drug Formulation" means that the Identical Drug Product has the same name(s) and amount(s) of active medicinal ingredients per dosage unit, excipients, components, and manufacturing process, as that of the Principal Product.

7. "Certificate of Listing of Identical Drug Product (CLIDP)" is the certificate issued by BFAD as proof that its pharmaceutical product has been officially listed with BFAD as identical, in terms of the manufacturer and of the pharmaceutical formulation, to the pharmaceutical product already covered by a Principal CPR.

8. "Principal Applicant" means the owner/holder of the pharmaceutical product being applied for a Principal CPR.

9. "Identical Drug Applicant" means the person, entity or establishment applying for the listing of its Identical Drug Product.

IV
Guidelines and Procedure

A. Principal CPR for the Principal Product

SECTION 1. Any owner/holder of a pharmaceutical product with a particular pharmaceutical formulation and with a duly issued and current CPR who/which can grant to third persons the authority or license to export, import, distribute, market or sell the same

pharmaceutical formulation, can apply for a Principal CPR.

SECTION 2. BFAD shall process the application for Principal CPR and shall require the Principal Applicant to surrender his/its duly issued and current CPR upon the issuance of the Principal CPR. The Principal CPR shall only be valid for the unexpired term of the surrendered CPR.

SECTION 3. Notwithstanding any existing procedure to the contrary, the Principal CPR shall be entitled to automatic renewal upon full compliance with the following conditions:

a. The Principal Product is registered for general or restricted use;

b. The registrant has a current and valid License to Operate;

c. Filing of an Application for Renewal of Principal CPR at least ninety (90) days before the expiration of the Principal CPR. Provided that, any Application for Renewal that will be filed within sixty (60) days after the expiration date of the Principal CPR shall be subject to a fifty percent (50%) surcharge based on the 5-year renewal fee;

d. Execution of an affidavit of undertaking, which shall be incorporated in or attached to the Application for Renewal, signed either by the registrant's medical director or pharmacist, that: (1) there is no change in the registrant's address/location, manufacturer, pharmaceutical formulation, excipients, dosage form, strength, therapeutic indication, manufacturing process, labeling or commercial presentation and packaging of the Principal Product covered by the Principal CPR; (2) acknowledges and agrees that in the event that there is an unauthorized change in the manufacturer, pharmaceutical formulation, excipients, dosage form, strength, therapeutic indication, manufacturing process, labeling or commercial presentation and packaging of the Principal Product:

i) BFAD may automatically suspend the LTO and/or Principal CPR of the Principal Product;

ii) It will voluntarily recall its Principal Product from the market;

iii) It will indemnify and/or hold BFAD free and harmless against any and all third party claims and/or actions; and

e. Payment of the renewal fee.

The Principal CPR shall be deemed automatically renewed upon the submission with BFAD of the duly accomplished Application for Renewal, affidavit of undertaking, and proof of payment of the renewal fee. The renewal of the registration is for the duration of five (5) years starting on the date of the expiration of the Principal CPR. For purposes of demonstrating the automatic renewal of the Principal CPR, BFAD shall require the presentation of the Principal CPR, on which the BFAD seal shall be stamped-marked to indicate its renewal.

SECTION 4. No CPR of an owner/holder of a pharmaceutical product with a particular pharmaceutical formulation who/which grants to third persons the license to export, import, distribute, market or sell the same pharmaceutical formulation, shall be renewed until and unless it is registered as Principal CPR under this Order. An expired CPR that has not been renewed within the 60-day grace period cannot be subject of a renewal application and shall be considered an initial application for Principal CPR.

SECTION 5. Any initial application for Principal CPR shall be obliged to comply with the requirements established by BFAD for a regular CPR.

SECTION 6. If there is any change in the manufacturer of the finished product and/ or pharmaceutical formulation of the Principal Product, the Principal CPR owner/holder shall inform BFAD, which will determine whether or not the change in the manufacturer and/or Principal Formulation will affect (a) the identity of formulation between the Principal Product and the Identical Drug Product; or (b) the listing of any Identical Drug Product under the Principal CPR.

B. Listing for Identical Drug Product

SECTION 1. No Identical Drug Product shall be distributed, marketed, sold, and/or offered for sale unless listed as such under this Order.

SECTION 2. An Identical Drug Applicant shall list his/its Identical Drug Product under a Principal CPR by submitting an application containing the following information and/or documents, among others:

a. Photocopies of the respective current and valid Licenses to Operate (LTOs) of the Identical Drug Applicant and the Principal CPR owner/holder;

b. Photocopy of the current and valid Principal CPR;

c. Authenticated copy of the duly notarized Distributorship Agreement, License Agreement or other written contract between the Principal CPR owner/holder and the Identical Drug Applicant authorizing the latter to deal in the Identical Drug Product; and

d. Affidavit of undertaking that (i) there is no change in the manufacturer of the finished product and of the pharmaceutical formulation of the Identical Drug Product vis-a-vis the Principal Product; and (ii) he/it acknowledges and agrees to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from any unauthorized change in the manufacturer of the finished product and/or pharmaceutical formulation of the Identical Drug Product.

Notwithstanding any existing rule or regulation to the contrary, the Identical Drug Applicant shall not be required to submit technical documents in the evaluation of the Identical Drug Product that have already been submitted in the evaluation of the Principal Product covered by the Principal CPR.

SECTION 3. Upon the listing of the Identical Drug Product under the Principal CPR and the issuance of the CLIDP, it shall be provided that same Drug Registration (D.R.) number assigned to the Principal Product, followed by a suffix that identifies it as being registered and listed under the Principal CPR and by a number denoting the number of Identical Drug Products already issued under the same Principal CPR.

Example: