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

SENTRONG SIGLA
Health ang unat

7 December 2005

ADMINISTRATIVE ORDER
NO. 2005-0030

SUBJECT: **Guidelines and Procedure For the Automatic Renewal of the Certificate of Product Registration issued by the Bureau of Food and Drugs**

I. RATIONALE

In the performance of the State's duty to protect and promote the right to health of the people and instill health consciousness among them (Section 15, Article II, 1987 Constitution), 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, among other things, to establish an effective system in the registration, monitoring and regulation of products.

The effectivity and efficiency in the registration system of products, however, have been affected and hampered by, among other things, the deluge of applications for renewal of Certificates of Product Registration (CPR) with the Bureau of Food and Drugs (BFAD).

It has been further observed that, regardless of whether or not there are changes in the ownership, address, ingredients, manufacturer, pharmaceutical formulation, labeling, packaging, and/or other documents submitted with the BFAD, the applications for renewal of CPR go through the same procedure, thereby requiring the expenditure of manpower and precious government resources.

Therefore, allowing the automatic renewal of the CPR under certain terms and conditions will permit BFAD to direct more time and effort to new product registrations while ensuring continued availability of products at competitive prices.

II. PURPOSE AND OBJECTIVE

The purpose of this Order is to: (a) simplify and expedite the renewal of the registration of products requiring CPR from the BFAD; (b) ascertain and establish responsibility in the renewal of the CPR; and (c) assist BFAD in strengthening the conduct of its post-market surveillance of products requiring CPR.

III. GUIDELINES AND PROCEDURE

Section 1. Any product is eligible for automatic renewal of CPR with BFAD provided that:

(a) The registrant has a current and valid License to Operate (LTO) with attached list of products manufactured/distributed, its traders, and products/activities covered under the LTO. Provided that, for dangerous drugs, a current and valid License to Handle controlled substances shall also be required;

(b) The product is covered by a current and valid CPR. Provided that, for pharmaceutical products, only those registered for general or restricted use are eligible for automatic renewal of registration;

(c) There are no deficiencies that need to be corrected before the renewal of the CPR can be granted.

Section 2. The following procedure should be followed in order that the CPR shall be deemed automatically renewed:

(a) The registrant shall file an Application for Renewal of CPR at least ninety (90) days before the expiration of the CPR. Provided that, any Application for Renewal that will be filed within sixty (60) days after the expiration date of the CPR shall be subject to a fifty percent (50%) surcharge based on the fee for the chosen renewal period;

(b) The CPR can be renewed, depending on the choice of the registrant, for the duration of either one (1) year, three (3) years, or five (5) years; and

(c) Execution of an affidavit of undertaking, which shall be incorporated in or attached to the Application for Renewal, signed by the registrant's President/General Manager or its authorized liaison officer, and if the registrant is a pharmaceutical company, its medical director or pharmacist, that:

(1) there is no change in the ownership, registrant's address/location, manufacturer, ingredients, pharmaceutical formulation, dosage form, strength, therapeutic indication, manufacturing process (if applicable), labeling or commercial presentation and packaging of the product covered by the CPR;

(2) the registrant acknowledges and agrees that in the event that there is an unauthorized change in the ownership, its address/location, manufacturer, ingredients, pharmaceutical formulation, dosage form, strength, therapeutic indication, manufacturing process (if applicable), labeling or commercial presentation and packaging of the product:

i. BFAD may automatically suspend the LTO and/or CPR of the product;

ii. It will voluntarily recall its 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

(d) Payment of the renewal fee.

Section 3. The 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. For purposes of demonstrating the automatic renewal of the CPR, BFAD shall require the presentation of the CPR, on which the BFAD seal shall be stamp-marked to revalidate and indicate its renewal.

Section 4. 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 the registration the product.

IV. RENEWAL FEES

BFAD is hereby authorized to charge the appropriate fees in the automatic renewal of the CPR. The renewal fees may be revised periodically upon the recommendation of the Director of BFAD and approved by the Secretary of Health.

V. 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.

VI. REPEALING CLAUSE

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

VII. EFFECTIVITY

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

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