

**[DOH ADMINISTRATIVE ORDER NO. 2005-0030,
December 07, 2005]**

**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 registration 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