



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



January 3, 2005

ADMINISTRATIVE ORDER  
NO. 2005-0001

**SUBJECT: Revised Policies and Guidelines  
Governing Patent and Trade Secret  
Rights in relation to the Registration of  
Pharmaceutical Products**

**I. RATIONALE**

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

To achieve such objective, the State was mandated to (a) 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 (Section 11, Article XIII, 1987 Constitution); and (b) establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems (Section 12, Article XIII, 1987 Constitution).

In view thereof, and to establish an effective drug regulatory system, Section 26(a), in relation to Section 21(b) and 11 (j) of Republic Act No. 3720, as amended by Executive Order No. 175, otherwise known as the "Food, Drugs and Devices and, Cosmetic Act", and consistent with Republic Act No. 6675, otherwise known as the "Generics Act of 1988", Administrative Order No. 67, series of 1989 was promulgated to provide the rules and regulations for the registration of pharmaceutical products.

Nevertheless, in the registration of pharmaceutical products, issues concerning intellectual property rights have been raised that have effectively impeded the achievement of the abovementioned constitutional

mandate and objectives. It is clear, however, from the 1987 Constitution and the aforementioned laws, rules and regulations that the Department, through the Bureau of Food and Drugs (BFAD), is mandated only to ensure the safety, efficacy and good quality of pharmaceutical products applied for registration. It has no mandate at all to pass upon intellectual property matters since it does not have the legal authority, resources and competence to do so.

Meanwhile, pursuant to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, issues pertaining to intellectual property rights, particularly patent rights, trademarks, trade names, copyrights, and unfair competition, are properly lodged with either the Intellectual Property Office (IPO) or a court of law with competent jurisdiction on the subject matter.

## **II. PURPOSE AND OBJECTIVE**

On 30 September 2004, this Department issued Administrative Order No. 170, series of 2004 to establish the policies and guidelines governing intellectual property rights in relation to the registration of pharmaceutical products.

After consultation with various stakeholders in the pharmaceutical industry, this Department deemed it necessary to revise A.O. No. 170, series of 2004.

Henceforth, the purpose of this Order is to establish and revise the existing policies and guidelines governing intellectual property rights and the registration of pharmaceutical products in recognition of the respective mandate, authority, and jurisdiction of this Department, through BFAD, the IPO, and the court of law with competent jurisdiction over intellectual property rights disputes. In this Order, "intellectual property rights" means patents and trade secret rights over a pharmaceutical product.

In issuing this Order, this Department, through BFAD, hereby reiterates and consistently adopts its mandate and responsibility to ensure the safety, efficacy and good quality of pharmaceutical products applied for registration.

## **III. GENERAL GUIDELINES**

This Department, through BFAD, therefore adopts the ensuing guidelines for the guidance and compliance of all concerned:

1. All applications for registration of pharmaceutical products filed with the BFAD shall be evaluated with regard their safety, quality, and efficacy in accordance with existing rules on product (CPR) registration.

2. The acceptance for CPR applications by BFAD shall not be interpreted, nor construed, as an approval, endorsement, or representation that the applicant has legal right or title over any intellectual property attached to the pharmaceutical product applied for.

3. The applicant, by himself, or if a juridical entity, through its duly authorized representative, shall execute a notarized affidavit of undertaking, stating that:

- (a) should the IPO or court of law of competent jurisdiction decide, with finality, that the applicant has no intellectual property right involving, or attached to, the pharmaceutical product, then any CPR issued to the product in question shall be deemed automatically cancelled and/or revoked; and
- (b) he acknowledges and agrees to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the registration of the pharmaceutical product concerned.

4. All new applications for CPR on pharmaceutical products shall be posted at the BFAD website at least for a period of thirty (30) days from the filing of such application containing; among others, the application number, the generic name and brand name, if any, of the product and the name of the applicant.

5. In the event that any interested party notifies BFAD in writing of any alleged prior or existing intellectual property right over the said product, BFAD shall immediately respond to said party, in writing, that intellectual property matters are beyond the legal mandate of BFAD and that their proper recourse should be from the IPO or the appropriate courts of competent jurisdiction.

6. Under no circumstance shall the filing of any such notification or the posting of any new application in the BFAD website be the reason or cause to suspend, delay, or otherwise adversely affect the processing of the application for, and the issuance of the CPR until and unless BFAD is restrained or enjoined by the proper authorities from doing so. In this instance, "proper authority" shall only pertain to the IPO or courts of law with competent jurisdiction over the said subject matter.

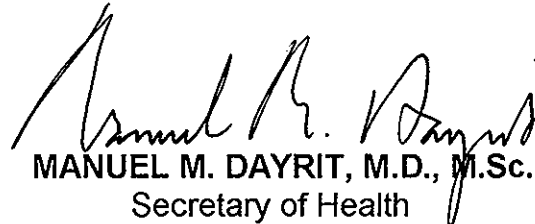
7. Consequently, the following annotation, "*The effectivity of this Certificate of Product Registration (CPR) will be the date after the patent of this product expires*", previously inserted in the CPR covering pharmaceutical products shall be deemed superfluous as if the same were not written. Henceforth, any other annotation of similar import that establishes a linkage between matters on intellectual property and the effectivity of the CPR or any other restriction or condition outside the mandate or authority of BFAD shall not be countenanced.

#### IV. REPEALING CLAUSE

A.O. No. 170, series of 2004 and all other administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/ revoked accordingly.

#### V. EFFECTIVITY

This Order shall take effect immediately after publication in two (2) newspapers of general circulation.

  
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Secretary of Health