

**[ DOH ADMINISTRATIVE ORDER NO. 2005-0001,  
January 03, 2005 ]**

**REVISED POLICIES AND GUIDELINES GOVERNING PATENT AND  
TRADE SECRET RIGHTS IN RELATION TO THE REGISTRATION OF  
PHARMACEUTICAL PRODUCTS**

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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.