



GENERAL OFFICE OF HEALTH REGULATION, SUPERVISION AND CONTROL
DEPARTMENT FOR THE REGULATION AND CONTROL OF PHARMACEUTICAL AND RELATED
PRODUCTS
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*Ministry of Public Health and
Social Assistance*

Guatemala, January 20, 2008.

**MINISTRY OF PUBLIC HEALTH AND SOCIAL ASSISTANCE,
DEPARTMENT FOR THE REGULATION AND CONTROL OF PHARMACEUTICAL AND
RELATED PRODUCTS**

WHEREAS:

According to section 177 quinquies of the Intellectual Property Law and its amendment through Congressional Decree 11-2006 of the Republic of Guatemala, the corresponding administrative authority will apply measures directed to avoiding the commercialization of a Sanitary Registry for a patent protected product, without the patent holder's proper authorization;

WHEREAS:

It is necessary to have a database containing patents that are registered and currently in force in the country, made up of the patents object of protection; this database will consist of the information presented by the patent holders and may be consulted by the interested parties, providing information on patents that are currently in force in the chemical field that shall include pharmaceutical products or their approved uses and to provide the protection of intellectual property established by Law;

THEREFORE:

In exercise of the powers conferred by Section 35, literal a), of Government Agreement number 115-99, Internal Organic Regulation of the Ministry of Public Health and Social Assistance and according to that stated by Section 177 quinquies of the Intellectual Property Law;

THE MINISTRY AGREES:

To issue the
following:

**REGULATION No. 55-2008 Creation of an Invention
Patent Database Covering Products Object of Intellectual Property Protection**

Section 1. The Department for the Regulation and Control of Pharmaceutical and Related Products creates a database of patents currently in force in the country that covers pharmaceutical products or the approved use of such, which is made up of information presented by patent holders, their legal representatives or agents in the country.

Section 2. The Department calls for all patent holders requesting intellectual property protection to present the following written information, signed and sealed by the legal representative, in the case of legal entities, or the name of the owner:

- a) Registration Certificate of the patent in the Intellectual Property Registry of Guatemala, issued within a maximum period of thirty calendar days as of its date of submittal;
 - b) Identification of the approved molecule, product or use;
 - c) International Common Denomination (DCI for its initials in Spanish);
 - d) Identification of the Trademark with which the approved product or products, if any, are or will be commercialized, and the corresponding Sanitary Registry numbers, if any;
 - e) Patent holder's full name;
 - f) Name of the patent holder's Legal Representative or Agent in Guatemala;
 - g) Indication of the address of service in the country; and
- Special observations added due to their importance.

Section 3. Once the certificate has been received, the Department will update the database and provide the information to all users through physical or electronic means. The Department will establish the procedure to access the information.

Section 4. The Department will be responsible for the database management, guaranteeing its reliability, integrity and security.



Dr. Jorge Alejandro Villavicencio Álvarez

Head of the Department for the Regulation and Control
of Pharmaceutical and Related Products

