

**AMENDMENT OF DECREE No. 88-2001,
REGULATIONS UNDER THE LAW ON PATENTS FOR INVENTIONS,
UTILITY MODELS AND INDUSTRIAL DESIGNS**

DECREE No. 16-2006, adopted on March 9, 2006

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THE PRESIDENT OF THE REPUBLIC OF NICARAGUA,

WHEREAS

I

The National Assembly of Nicaragua adopted the Free Trade Agreement between Central America, the United States of America and the Dominican Republic (CAFTA-DR), by means of Legislative Decree No. 4371, published in La Gaceta No. 199 of October 14, 2005.

II

The President of the Republic ratified the Free Trade Agreement between Central America, the United States of America and the Dominican Republic (CAFTA-DR), signed in the city of Washington, D.C., on August 5, 2004, by means of Decree No. 77-2005, published in La Gaceta No. 203 of October 20, 2005.

III

The text of the Free Trade Agreement (CAFTA-DR) envisages in Chapter Fifteen, Article 15.10, measures related to certain regulated goods, which must be aligned with the legal, commercial and administrative framework.

IV

It is necessary to deal with intellectual property aspects and to ensure the implementation of the immediate undertakings to be fulfilled by Nicaragua deriving from the Free Trade Agreement signed, particularly with regard to guaranteeing normative consistency between the normative aspects of the Agreement and our national legislation.

V

Law No. 354, Law on Patents for Inventions, Utility Models and Industrial Designs, published in La Gaceta No. 179 of September 22, 2000, provides in Article 125 for protection for trade secrets or undisclosed information and test results, submitted to the competent national authority to secure approval for the commercialization of pharmaceutical products or agricultural chemicals containing a new chemical component.

By virtue of the powers conferred on him by the Political Constitution,

HAS ISSUED

The following:

DECREE

Amendment of Decree No. 88-2001, Regulations under the Law on Patents for Inventions, Utility Models and Industrial Designs

Article 1. Amend Article 55 of Decree No. 88-2001, Regulations under the Law on Patents for Inventions, Utility Models and Industrial Designs, published in La Gaceta No. 184 of September 28, 2001, to read as follows:

“Article 55.- Protection of trade secrets or undisclosed information and test results

Trade secrets shall be protected indefinitely and shall combine the following elements: they are secrets insofar as they are not part of the main body or in the precise configuration and pooling of their components, generally known or easily accessible by persons operating in the circles in which the type of information in question is generally used; they possess commercial values as secrets; and they have been the subject of reasonable measures, in the circumstances, for keeping them secret, taken by the person exercising legitimate control over them.

In the event that the submission of undisclosed data on the safety and effectiveness of a new pharmaceutical product or agricultural chemical is a requirement for the approval of the same, the national authority, in accordance with Article 125 of Law No. 354, Law on Patents for Inventions, Utility Models and Industrial Designs, shall guarantee that third parties who do not have the authorization of the person providing the information may not use, for commercial purposes, the information or the approval granted to the person presenting the information, during a period of five years for pharmaceutical products and ten years for agricultural, chemicals, pursuant to the provisions of Article 15.10 of the Free Trade Agreement between Central America, the United States of America and the Dominican Republic (CAFTA-DR).

“National authority” shall be understood as the Pharmacy Division of the Ministry of Health (MINSa), for new pharmaceutical products for human use and/or the Department for Agricultural and Livestock Protection and Health (DGPSA) of the Ministry for Agriculture, Livestock and Forests (MAGFOR), for new pharmaceutical products for veterinary use and agricultural chemicals.”

Article 2. The ministers of the government agencies indicated in the previous article shall issue their respective administrative procedures within their purview, in accordance with the functions vested in them by the respective Law, within a maximum of 15 days, to ensure effective compliance with the provisions of the Free Trade Agreement between Central America, the United States of America and the Dominican Republic (CAFTA-DR), with regard to the protection of undisclosed information and test results; these procedures shall be published in La Gaceta.

Article 3. This Decree shall enter into force upon publication in La Gaceta.

Done in the city of Managua, at the Presidential Residence, on March 9, 2006. **Enrique Bolaños Geyer**, President of the Republic of Nicaragua. **Alejandro Argüello Choiseul**, Minister for Industrial Promotion and Trade.
