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WORLD INTELLECTUAL PROPERTY ORGANIZATION

GENEVA

STANDING COMMITTEE ON THE LAW OF PATENTS

Eleventh Session Geneva, June 1 and 2, 2005

ADDENDUM TO ACCREDITATION OF NON-GOVERNMENTAL ORGANIZATIONS

Document prepared by the Secretariat

- 1. Document SCP/11/2, entitled "Accreditation of Non-Governmental Organizations" refers to the request of four non-governmental organizations to be granted observer status in the sessions of the Standing Committee on the Law of Patents (SCP), according to its Rules of Procedure (see document SCP/1/2, paragraph 6).
- 2. The Annex to the present document contains information received from the Generic Pharmaceutical Association of the United States (GPhA) and the Mexican National Association of Pharmaceutical Manufacturers (ANAFAM), which have also requested observer status for future sessions of the SCP.
 - 3. The SCP is invited to take a decision on the request for accreditation of the non-governmental organizations referred to in the present document, together with the non-governmental organizations referred to in document SCP/11/2, entitled "Accreditation of Non-Governmental Organizations."

[Annex follows]

ANNEX

US GENERIC PHARMACEUTICAL ASSOCIATION (GPhA)

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.

GPhA members manufacture more than 75% of all affordable pharmaceuticals dispensed in the United States. Our products are used in more than one billion prescriptions every year.

The Association maintains its headquarters in Arlington, VA from which its day-to-day business is conducted. The GPhA represents the industry and its member companies through the participation in regulatory, scientific and legislative forums on matters that are of mutual interest and concern to its members.

GPhA was established in Washington, D.C. on June 20, 2000.

GPhA Mission

The Generic Pharmaceutical Association (GPhA) was organized to:

- Promote the common interests of its members and the general welfare of the pharmaceutical industry;
- Prepare and disseminate among its members and others, accurate and reliable information concerning the industry, its products, needs and requirements;
- Participate in international, federal, state and municipal legislative, regulatory and administrative proceedings with respect to laws, rules and orders affecting the pharmaceutical industry;
- Participate in scientific research and product development with intent to increase consumer access to generic products and;
- Raise awareness and visibility of the significant benefits and value of generic drugs to the consumer.

List of Officers

Kathleen Jaeger President & CEO

Christine Simmon Vice President of Public Affairs and Development

Gordon Johnston Vice President of Regulatory Affairs

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MEXICAN NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (ANAFAM)

HEADQUARTERS: Mexico City, D.F.

DATE AND PLACE OF ESTABLISHMENT:

The Mexican National Association of Pharmaceutical Manufacturers, A.C. (ANAFAM) was originally established under the name of the National Association of Manufacturers of Chemical, Pharmaceutical and Medicinal Products on May 21, 1945, in Mexico City, D.F.

On October 5, 1963, the name was changed to the Mexican National Association of Pharmaceutical Manufacturers, A.C. in Mexico City, D.F.

DESCRIPTION OF THE ASSOCIATION:

ANAFAM is a body set up to represent a group of pharmaceutical companies established in Mexico, able to project an image of technological and entrepreneurial solidity, and exercising a positive influence on the main players in the relevant environment, in a constant search to expand its markets in order to promote increased competitiveness and strengthen its members.

ANAFAM currently comprises more than 30 laboratories of national origin with a total market share of 19.9 per cent in terms of units and 14.5 per cent in value terms* (*Information Management System, Dictionary 2003), and is the main health sector supplier, with an overall market share in terms of units of about 50 per cent. These laboratories are the most representative in the national market and, in 2002, their sales totaled approximately US\$1,204 million.

The current share of the National Pharmaceutical Industry in the government market is about 80 per cent, while that of multinationals is 20 per cent. In the private market, the National Industry share is inversely proportional, i.e. 20 per cent, and for the multinational industry 80 per cent.

OBJECTIVES:

- To promote the development of the National Pharmaceutical Industry with a unified stance in the face of the current challenges and circumstances prevailing in Mexico.
- To consolidate itself as the main supplier of high-quality accessible drugs in the health sector.
 - To promote the National Generic Interchangeable Drugs Program.
 - To promote and develop the generation of employment.

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- To maintain a constant increase in investment in cutting-edge technology and pharmaceutical infrastructure in order to reach an international level of competitiveness.
- To retain its position as the main supplier of high-quality drugs at affordable prices in the health sector, acting as the major factor in achieving balanced prices for drugs.
- To consolidate the National Generic Interchangeable Drugs Program, both in the health sector and the private market, as well as developing the culture of these drugs.
 - To make the conduct of interchangeability tests in Mexico compulsory.
 - To increase the number of authorized third parties.
 - To make generic interchangeable drugs available at all points of sale in Mexico.
- To promote at the international level the development of competitiveness so as to project the National Pharmaceutical Industry globally.
 - To achieve compulsory acquisition in the health sector.
 - To make the updated catalog available through the distribution chain.

[End of Annex and of document]