

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[FDA 225-00-8002]

Memorandum of Understanding Between the Food and Drug Administration, the Department of Agriculture, and the University of Puerto Rico

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, the Department of Agriculture, and the University of Puerto Rico. The purpose is to establish a framework for collaboration on mutually agreed upon activities in scientific and regulatory areas.

DATES: The agreement became effective December 7, 2000.

FOR FURTHER INFORMATION CONTACT: Maritza Colon-Pullano, Office of the Commissioner (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4553.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 19, 2001
March 19, 2001.

Ann M. Witt

Ann M. Witt,
Acting Associate Commissioner for Policy.

[INSERT MOU]

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

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MEMORANDUM OF UNDERSTANDING

Between the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

and

THE UNIVERSITY OF PUERTO RICO
SAN JUAN, PUERTO RICO

The Food and Drug Administration (FDA), Food and Safety Inspection Service (FSIS), and the University of Puerto Rico (UPR), collectively referred to as the Parties, intend to establish cooperative training and research programs in the product areas subject to regulation by FDA and FSIS as follows:

I. PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to establish a framework for the Parties to collaborate on mutually agreed upon activities in the scientific and regulatory areas as they pertain to products falling within the statutory authority of FDA and FSIS. These efforts are intended to support and encourage the further understanding of science-based regulatory systems in the countries of the Americas and may lead to further cooperation among regulatory authorities.

II. GOALS OF MOU

The Parties intend to work together toward developing:

A. Educational programs covering U.S. laws, regulations and procedures as they pertain to products falling within the statutory authority of FDA and FSIS.

B. Outreach programs designed to recruit Hispanic professionals from the United States and to enhance and sustain the qualifications of professionals in the Americas.

C. Cooperative activities among other academic institutions, authorities, and organizations (e.g., PAHO) in the Americas.

D. Cooperative partnerships in the Americas among government regulatory agencies, academic institutions, regulated industries, and consumers for dissemination and exchange of information developed at UPR through this MOU.

III. ORGANIZATION TO IMPLEMENT MOU

An organization will be formed to implement this MOU that includes representatives from FDA, FSIS, and UPR. The organization will operate according to terms agreed to by the Parties.

IV. RESOURCE OBLIGATIONS

This MOU describes in general terms the basis upon which the Parties intend to cooperate in these activities. It does not create binding, enforceable obligations against any Party.

All activities undertaken pursuant to this MOU are subject to availability of personnel, resources, and appropriated funds.

V. OTHER AGREEMENTS OR ARRANGEMENTS

This MOU does not affect or supercede any existing or future agreements or arrangements among any of the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to the purpose of this MOU.

VI. NAMES AND ADDRESSES OF PARTICIPATING PARTIES

- A. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
- B. Food Safety and Inspection Service
14th and Independence Avenue, S.W.
Washington, D.C. 20250
- C. University of Puerto Rico
San Juan, Puerto Rico 00936-4984

VII. LIAISON OFFICERS

- A. Liaison Office for FDA:

THE OFFICE OF INTERNATIONAL PROGRAMS

B. Liaison Office for FSIS:

THE OFFICE OF MANAGEMENT

C. Liaison Office for UPR:

THE OFFICE OF THE PRESIDENT

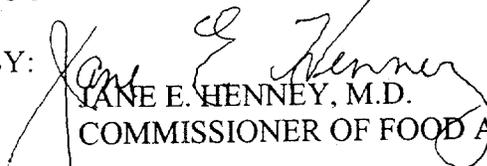
VIII. DURATION OF MOU

This MOU shall become effective upon signature of all the Parties and will continue in effect for five (5) years. It may be extended by mutual written agreement of the Parties in writing. It may be modified by mutual consent or terminated by either Party upon a 30-day advance notice to the other Party.

IX. This MOU and all associated agreements will be subject to applicable federal and state laws and regulations.

FOOD AND DRUG ADMINISTRATION

BY:


JANE E. HENNEY, M.D.
COMMISSIONER OF FOOD AND DRUGS

DATE: Dec 7, 2000

FOOD SAFETY AND INSPECTION SERVICE

BY:


THOMAS J. BILLY
ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE

DATE: DEC 7, 2000

THE UNIVERSITY OF PUERTO RICO

BY:


NORMAN I. MALDONADO, M.D.
PRESIDENT OF THE UNIVERSITY OF PUERTO RICO

DATE: DEC 7, 2000