

**MEMORANDUM OF UNDERSTANDING**  
between  
**THE UNITED STATES FOOD AND DRUG ADMINISTRATION**  
and the  
**UNIVERSITY SYSTEM OF MARYLAND**

**I. PURPOSE**

The United States Food and Drug Administration (FDA) and the University System of Maryland (USM) (the Parties) have a shared interest in scientific progress in the diverse disciplines that directly and indirectly affect human and animal health and medicine. The Parties also endorse scientific training for faculty, students and staff to foster a well-grounded foundation in interdisciplinary fields in which academia and government share mutual interest.

This Memorandum of Understanding (MOU) establishes terms of collaboration between FDA and USM to support these shared interests that can be pursued through a variety of programs including collaborative research, public outreach, extension activities, cooperative international initiatives, disciplinary training, and exchange of scientists and staff, including sabbaticals, postdoctoral fellowships, and student internships.

**II. BACKGROUND**

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301). In fulfilling its responsibilities under the Act, FDA among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods and cosmetics (Appendix A). To accomplish its mission, FDA must stay abreast of the latest developments in research and also communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the USM will greatly contribute to FDA's mission.

USM is one of Maryland's most valuable assets and adds immeasurably to the quality of life in the state and beyond. The nation's 12th largest university system, USM's network of 13 institutions (Appendix B) enrolls nearly 130,000 students worldwide in 600 degree programs delivered in classrooms, laboratories, education centers, and online. The USM's nationally ranked programs, leading-edge research collaborations, and innovative business partnerships provide an environment to support diverse multidisciplinary exchanges with FDA. The scientific, public health and policy expertise within FDA provide opportunities for collaborations that support the USM mission and strategic themes to provide access to high-quality education, research discovery, and knowledge-based services responsive to both the promises and demands of the state and the nation in the new century.

**III. SUBSTANCE OF THE AGREEMENT**

This MOU forms the basis for development of scientific collaborations, outreach and educational initiatives and intellectual partnerships between FDA and USM. The types of activities expected to develop from this MOU include:

- Exchanges between university faculty and staff and FDA scientists and staff;
- Educational opportunities for qualified students (graduate and undergraduate), staff members, and faculty members in the Parties' laboratories, classrooms and offices;
- Joint meetings for education and research;
- Research collaborations;
- Cooperative international activities including outreach; and

- Sharing of unique facilities and equipment for increased cost efficiencies for scientific endeavors.

Under this Agreement, joint efforts will be undertaken to obtain grants and other extramural funds to support collaborative research and training as permitted under appropriate statutory authority. Before any specific collaboration is initiated or implemented, the parties shall identify priorities, topics of mutual interest, and develop separate, written agreements for collaboration and sharing of resources. Where applicable, these agreements shall incorporate by reference this memorandum of understanding. FDA may enter into a contract, grant or cooperative agreement with USM to the extent authorized by law and available appropriations. The terms and conditions of any such awards will be in accordance with applicable federal law and regulations, and shall be negotiated and executed by appropriate representatives of institutions within the USM and FDA.

A. FDA agrees to:

For programs agreed to in writing, and in advance by both parties, FDA may, as permitted by applicable statutes and regulations and subject to the availability of funds, and as it deems appropriate, offer USM the following:

- Laboratory and/or office space in support of activities under this agreement.
- Access to facilities and equipment, including necessary training and guidance, in so far as such use does not interfere with the primary mission of either party.
- Active participation in establishing collaborative research, education, extension and outreach efforts with faculty, students, and staff within USM institutions.
- Willingness to participate in courses and seminars within USM, based on availability of resources.
- Continuing and frequent communication with faculty and staff.
- Openness and welcome to faculty, staff, and students wishing to visit FDA laboratories.
- Promulgation and communication of identified collaborative efforts through appropriate means.

B. University System of Maryland agrees to:

For programs agreed to in advance by both parties, USM may offer FDA the following:

- Laboratory and/or office space in support of activities under this agreement at identified institutions.
- Access to facilities and equipment, including necessary training and guidance, in so far as such use does not interfere with the primary mission of either party.
- Active participation in establishing collaborative research, education, extension and outreach efforts with FDA scientists and staff.
- Continuing and frequent communication with FDA scientists and staff.
- Openness and welcome to FDA scientists and staff wishing to visit relevant USM programs and laboratories.
- Promulgation and communication of identified collaborative efforts through appropriate means.
- Adjunct, affiliate and research faculty appointments for appropriate FDA professional staff, provided that appointment of such candidates will advance specific programmatic objectives of the parties as appropriate, and provided that such appointments comply with university policies on appointment of faculty/affiliates.

C. It is mutually agreed that:

In an effort to enhance collaborative interactions and communication between both institutions, FDA and USM will collaborate in the development of regular workshop where faculty from all the institutions within the USM and FDA scientists and staff share information about on going research, education, extension, and outreach efforts of mutual interest.

D. Additionally it is agreed that:

1. Rights to any inventions resulting from collaborative research will be determined based on current U.S. Government patent regulations and any other applicable statutes and regulations.
2. Institutions within USM and FDA may decide to enter into Cooperative Research and Development Agreements (CRADA) specific to particular collaborative projects. The terms of such CRADAs will address Intellectual Property rights.
3. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements, or to the extent such disclosure is permitted by law.
4. Each party will comply with the other party's security procedures and policies regarding access to and use of facilities. Either party may restrict or limit access to its property and facilities, at any time, for any reason. USM individuals participating in activities under this MOU on FDA property will comply with all applicable federal statutes and regulations.
5. It is recognized that from time to time FDA and institutions within USM will be sharing in expenses and may require compensation of either party by the other. As research projects are developed, details of how costs are to be shared will be agreed to in advance under other contractual mechanisms as appropriate and in compliance with all applicable federal requirements.
6. This agreement may be amended any time upon mutual agreement between the parties in writing.

IV. FINANCES AND RESOURCES

The foregoing represents the broad outline of the parties' present intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and the institutions within the USM. It does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU.

**V. CONTACTS**

The individual to whom all inquiries to FDA should be addressed is:

Mary I. Poos, PhD  
Director of Academic and Intellectual Partnerships  
Office of the Commissioner/Office of External Relations  
Food and Drug Administration  
PKLN 13B-17, HF-10  
5600 Fishers Lane  
Rockville MD 20857  
301-827-2825  
Mary.poos@fda.hhs.gov

The individual to whom all inquiries to USM should be addressed is:

Brian Darmody  
Special Assistant Vice Chancellor for Technology  
and Development  
University System of Maryland  
2133 Lee Building  
College Park, Maryland 20742  
301-405-1990 301-405-8386 (fax)  
bdarmody@umd.edu

**VI. PERIOD OF AGREEMENT**

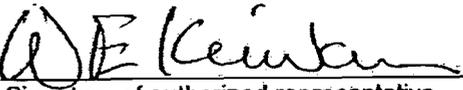
This agreement becomes effective upon acceptance by both parties and will continue in effect for five (5) years and may be renewed upon mutual agreement of the parties.

**VII REGULATIONS**

This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA, USM and the institutions within the USM operate.

AGREED TO:

UNIVERSITY SYSTEM OF MARYLAND

BY:   
Signature of authorized representative

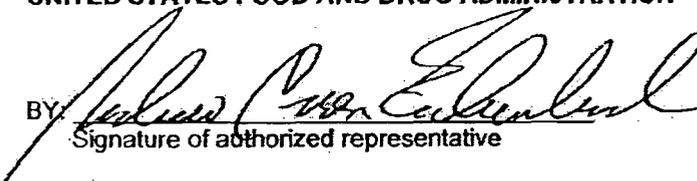
July 12, 2007  
Date

William E. Kirwan, PhD  
Print name

Chancellor, USM  
Title

[other signatories -- Individual Institutions within the USM]

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY:   
Signature of authorized representative

July 12, 2007  
Date

Andrew C. von Eschenbach, MD  
Print name

Commissioner, FDA  
Title

APPENDIX A

FDA Centers/Offices

The U.S. Food and Drug Administration (FDA) is comprised of six product-oriented centers, in addition to a nationwide field force. FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. It is one of the oldest federal agencies whose primary function is consumer protection. The agency touches and directly influences the lives of everyone in the United States. FDA is recognized internationally as the leading food and drug regulatory agency in the world. Many foreign nations seek and receive FDA's help in improving and monitoring the safety of their products. FDA is part of the Executive Branch of the United States Government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS).

FDA Centers/Offices include:

**Office of the Commissioner (OC)**

OC is committed to providing the overall scientific and regulatory policies for the entire agency, including special FDA initiatives. OC includes the Office of International Programs and Special Initiatives, the Office of Science and Health Coordination, the Office of Women's Health, the Office of Orphan Product Development, the Office of Combination Products, the Critical Path Initiative, the Office of Policy and Planning and the Office of Counterterrorism Policy and Planning

**Center for Biologics Evaluation and Research (CBER)-**

CBER is committed to advancing the public health through innovative regulations that ensure the safety, effectiveness and timely delivery to patients of biological products. CBER protects and enhances public health through the regulation of biological and related products including blood, vaccines, tissue, allergenic and biological therapeutics.

**Center for Drug Evaluation and Research (CDER)-**

CDER is committed to promoting and protecting public health by assuring that safe and effective drugs are available to Americans. Opportunities exist for faculty and students in pharmaceutical science, biochemistry, chemistry, biotechnology, bioengineering and chemical engineering, as well as many other scientific and engineering disciplines to engage with research and regulatory scientists in flexibly structured programs within the Center

**Center for Devices and Radiological Health (CDRH)-**

CDRH assures that new medical devices are safe and effective before they are marketed. The Center also monitors devices throughout the product life cycle, including a nationwide post market surveillance system, and assures that radiation-emitting devices meet radiation safety standards.

**Center for Food Safety and Applied Nutrition (CFSAN)-**

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

**Center for Veterinary Medicine (CVM)-**

CVM is a consumer protection organization that fosters public and animal health by approving safe and effective products for animals and by enforcing other applicable provisions of the Federal Food, Drug, and Cosmetic Act and other authorities.

**National Center for Toxicology Research (NCTR)-**

NCTR conducts peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs. This involves fundamental and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by the FDA. This research is aimed at understanding critical biological events in the expression of toxicity and at developing methods to improve assessment of human exposure, susceptibility and risk.

**Office of Regulatory Affairs (ORA)-**

ORA is the lead office for all Field activities of the Food and Drug Administration including inspection of food, feed, and medical product manufacturing, transport and storage facilities for compliance with existing law; as well as enforcement activities. It includes the Office of Criminal Investigations

APPENDIX B

Institutions within the University System of Maryland (USM)

The University System of Maryland (USM), a public corporation, is one of the State's most valuable assets. The nation's 12th largest university system, the USM's network of 13 institutions enrolls nearly 130,000 students worldwide in 600 degree programs delivered in classrooms, laboratories, education centers, and online. The USM's nationally ranked programs, leading-edge research collaborations, and innovative business partnerships provide opportunities that support the USM mission and the goals of the USM Strategic Plan as they prepare students for both the promises and demands of the new century.

University System of Maryland institutions include:

1. Bowie State University
2. Coppin State University
3. Frostburg State University
4. Salisbury University
5. Towson University
6. University of Baltimore
7. University of Maryland, Baltimore
8. University of Maryland, Baltimore County
9. University of Maryland, College Park
10. University of Maryland Eastern Shore
11. University of Maryland University College
12. University of Maryland Center for Environmental Science
13. University of Maryland Biotechnology Institute