detailed description of the record contents they are seeking.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under System Manager above, and identify the record and specify the information to be contested and corrective action sought with supporting justification to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State and from multistate financial institutions and insurers (or their agents).

ITEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–17642 Filed 9–6–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–8405]

Memorandum of Understanding Between the Food and Drug Administration and the University System of Maryland

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 FDA and the University System of Maryland to establish terms of collaboration to support shared interests that can proceed through a variety of programs including collaborative research, public outreach, cooperative international initiatives, interdisciplinary training, and exchange of scientists and staff through sabbaticals, postdoctoral fellowships, and student internships.

DATES: The agreement became effective July 12, 2007.

FOR FURTHER INFORMATION CONTACT: Mary I. Poos, Office of External Relations (HF–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2825.

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

Dated: August 29, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

FDA Record # 225-07-8405

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 disclsoure is governed by appropriate confidentiality disclosure agreements, or to the extent such dislcosure 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 inquires 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 AGREEEMENT

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.

FDA Record # 225-07-8405

AGREED TO:

UNIVERSITY SYSTEM OF MARYLAND

BY: _____ July 12, 2007
Signature of authorized representative — Date

William E. Kirwan, PhD — Chancellor, USM
Print name — Title

[other signatories -- Individual Institutions within the USM]

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ July 12, 2007
Signature of authorized representative — Date

Andrew C. von Eschenbach, MD — Commissioner, FDA
Print name — Title

FDA Record # 225-07-8405

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.

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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 exiting 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

[FR Doc. 07–4404 Filed 9–6–07; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0528]

''Guidance for Industry: Manufacturing Biological Intermediates and Biological Drug Substances Using Spore-Forming Microorganisms''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Manufacturing Biological Intermediates and Biological Drug Substances Using Spore-Forming Microorganisms'' dated September 2007. The guidance document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms'' dated February 2005.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets.ecomments* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Manufacturing Biological Intermediates and Biological Drug Substances Using Spore-Forming Microorganisms'' dated September 2007. The document provides guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

In the **Federal Register** of December 30, 2003, FDA published the direct final rule entitled ''Revision of the Requirements for Spore-Forming Microorganisms'' (68 FR 75116) and the accompanying proposed rule entitled ''Revision of the Requirements for Spore-Forming Microorganisms; Companion to Direct Final Rule'' (68 FR 75179) to modify the regulatory requirements for the manufacturing of biological products with spore-formers to allow greater manufacturing flexibility. The modifications were intended to provide alternatives to the then-existing requirements for separate, dedicated facilities and equipment for work with spore-forming microorganisms. In the **Federal Register** of May 14, 2004 (69 FR 26768), FDA published the ''Revision of the Requirements for Spore-Forming Microorganisms; Confirmation of Effective Date'' confirming the effective date of June 1, 2004, for the direct final rule.

In the **Federal Register** of February 24, 2005 (70 FR 9084), FDA announced the availability of the draft guidance dated February 2005. FDA received a few comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated February 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–17709 Filed 9–6–07; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial