FDA MOU No. 225-07-1000

VI. PERIOD OF AGREEMENT

This agreement becomes effective upon signature of both parties and will continue in effect for five (5) years. This agreement may be modified by mutual written consent or terminated by either party upon 120 days written notice. Not later than 120 days prior to the expiration of this agreement, each party will provide a recommendation regarding the extension of the agreement, including any modifications to the agreement.

APPROVED AND ACCEPTED FOR THE NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute

By: Eliz Nabel

Elizabeth G. Nabel, M.D.
Director
National Heart, Lung, and Blood Institute
National Institutes of Health

Date: 9.11.08

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research

By: [signature]

Jesse L. Goodman, M.D., M.P.H.
Center Director
Center for Biologics Evaluation and Research
Food and Drug Administration

Date: 9/8/08

[FR Doc. E8–25738 Filed 10–28–08; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]
[FDA No. 225–08–6000]

Memorandum of Understanding With the U.S. Army Medical Research Institute of Infectious Diseases

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) with the U.S. Army Research Institute of Infectious Diseases (USAMRIID). This MOU identifies the terms of collaboration between FDA and USAMRIID in the area of emergency preparedness. Specifically this MOU provides for the sharing of information and collaborative activities related to biological threat agents and diagnostics to detect such biological threat agents in order to assist both parties in more efficiently preparing for and responding to emergencies in which such diagnostic tests may be used.

DATES: The agreement became effective September 5, 2008.

FOR FURTHER INFORMATION CONTACT: Nancy J. Pluhowski, Senior Regulatory Health Scientist, Center for Devices and Radiological Health (HFZ–001), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3816, or

Dan Coffman, Business Plans and Programs Office, USAMRIID, 1425 Porter St., Fort Detrick, MD 21702–5011, 301–619–6886.

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: October 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

FDA Record No. 225-08-6000

MEMORANDUM OF UNDERSTANDING BETWEEN UNITED STATES FOOD AND DRUG ADMINISTRATION AND U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES

PURPOSE

This Memorandum of Understanding (MOU) between the U.S. Food and Drug Administration (FDA) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) (hereinafter also referred to as "Federal Partners" or "Partners") is established to formalize the development of collaborative activities between the two parties in the area of emergency preparedness. The FDA and the USAMRIID, both United States Federal Government entities, agree to share information related to biological threat agents and diagnostic tests for biological threat agents in order to assist both parties in preparing for emergencies in which these tests may be used. Sharing of information between FDA and USAMRIID will facilitate appropriate planning for and response to an emergency involving a biological threat agent. The purpose of the MOU is to enhance knowledge and efficiency by providing for more robust and efficient sharing of information and expertise between the Federal Partners.

BACKGROUND

a. FDA Center for Devices and Radiological Health (CDRH), Office of In Vitro Diagnostics (OIVD) is the lead FDA component responsible for the regulation of in vitro diagnostic products that are devices under the Federal Food, Drug, and Cosmetic Act (FFDCA). (See 21 U.S.C. 321(h).) FDA Center for Biologics Evaluation and Research (CBER), Office of Blood Research and Review (OBRR) is the lead FDA component responsible for maintaining a safe supply of blood and blood products and screening for biothreat agents that could be transmitted through blood transfusions. FDA CBER's Office of Cellular, Tissues and Gene Therapies (OCTGT) is the lead FDA component for maintaining a safe supply of tissues and screening for biothreat agents that could be transmitted through tissue transplantations.

b. USAMRIID is the lead Department of Defense (DoD) laboratory for developing tests to identify biological threat agents for diagnostic purposes. USAMRIID coordinates and collaborates with numerous organizations within and outside the DoD community.

c. Both Federal Partners are engaged in efforts to prepare for a potential emergency involving a biological threat agent. Responses to such emergencies may include the use of diagnostic tests.

FDA Record No. 225-08-6000

RESPONSIBILITIES/ACTIVITIES

In furtherance of the purpose identified, the Federal Partners agree to the following:

USAMRIID agrees to:

- Provide information on research and development efforts for diagnostic test development at USAMRIID and within the DoD.
- Provide information and subject matter expertise on biothreat agents that will assist FDA CDRH OIVD and CBER OBRR and OCTGT in evaluation and regulation of diagnostic tests for these agents.
- Participate in meetings to support these goals.

FDA agrees to:

- Provide information regarding application of requirements of the FFDCA to tests for biothreat agents developed or used by DoD, including pathways for use of tests not yet approved or cleared by FDA.
- Provide feedback to USAMRIID in support of DoD efforts to obtain FDA premarket approval, premarket clearance, or emergency use authorization, as applicable, for tests developed in the DoD.
- Participate in meetings to support these goals.

INFORMATION SHARING

The Federal Partners agree that any initial request for information under this MOU will be made by and transmitted to the Agency program liaisons. Subsequent communications pertaining to that issue may occur between other staff with the approval of the liaisons.

The Federal Partners agree that either Partner may decide not to share information or expertise in response to a particular request for information made according to this MOU, or to limit the scope of information and expertise sharing in response to a particular request. A decision not to share information in response to a specific request may be based on several factors, including, for example, the amount of resources necessary to fulfill the request, the reasonableness of the request, the responding Federal Partner's priorities, or legal restrictions, which are described in more detail below.

Proprietary or non-public information will not be disclosed under this MOU unless such disclosure is permitted by Federal law and the Federal Partners otherwise agree to share it. The Federal Partners recognize that information transmitted between them in any medium, and from any source, that contains any of the following types of information must be protected from unauthorized disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of

the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C. § 1905), the Privacy Act (5 U.S.C. § 552a), the Freedom of Information Act (5 U.S.C. § 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

RESOURCE OBLIGATIONS

This MOU represents the broad outline of the Federal Parties' present intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest. It does not create binding, enforceable obligations against either Partner. 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 Partners and does not affect the ability of the Partners to enter into other agreements or arrangements related to this MOU. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Federal Partners operate. Nothing in this MOU shall obligate the Federal Partners to any current or future expenditure of resources in advance of the availability of appropriations from Congress.

LIASON OFFICERS

To facilitate the activities carried out under this MOU, each Federal partner will establish a single agency administrative liaison and one or more agency program liaisons. The initial liaisons will be:

For FDA: CDRH will be the lead center:

Administrative Liaison (CDRH):
Nancy J. Pluhowski
Senior Regulatory Health Scientist, and
Director, Medical Device Fellowship Program
FDA, CDRH, Office of the Center Director
9200 Corporate Blvd Mail Code: HFZ-001
Rockville, MD 20850
Phone: 240-276-3816
Fax: 240-276-0652
Email: nancy.pluhowski@fda.hhs.gov

Administrative Liaison (CBER)
Carolyn Wilson, Ph.D.
Associate Director for Research
FDA Center for Biologics Evaluation and Research
8800 Rockville Pike

FDA Record No. 225-08-6000

Bethesda, MD 20892
Phone: 301-827-0481
Fax: 301-827-0449
Email: carolyn.wilson@fda.hhs.gov

Program liaison (CDRH):
Dr. Claudia Gaffey
Division of Microbiology Devices
FDA, CDRH, OIVD
2098 Gaither Road
Rockville, MD 20850-4017
Phone: 240 276-0718
Fax: 240- 276-0652
Email: claudia.gaffey@fda.hhs.gov

Program Liaisons (CBER)
Dr. Melissa A. Greenwald
Directory, Regulatory
Division of Human Tissues
Office of Cellular, Tissues, and Gene Therapies Branch
1410 Rockville Pike
Rockville, MD 20852
Phone: 301-827-2002
Fax: 301-827-2844
Email: melissa.greenwald@fda.hhs.gov

Dr. Hira Nakhasi
Supervisory Research Chemist
Office of Blood Research and Review
8800 Rockville Pike
Bethesda, MD 20892
Phone: 301-827-3008
Fax: 301-480-7928
Email: hira.nakhasi@fda.hhs.gov

For USAMRIID:

Administrative Liaison:
Dan Coffman
Business Plans and Programs Office
USAMRIID
1425 Porter Street
Fort Detrick, MD 21702-5011
Phone: 301-619-6886
Fax: 301-619-8379
Email: james.coffman@amedd.army.mil

FDA Record No. 225-08-6000

Program Liaisons:
LTC David Shoemaker
Diagnostic Systems Division
USAMRIID
1425 Porter Street
Fort Detrick, MD 21702-5011
Phone : 301-619-4734
Fax : 301-619-2492
Email: david.shoemaker@amedd.army.mil

Dr. David Norwood
Diagnostic Systems Division
USAMRIID
1425 Porter Street
Fort Detrick, MD 21702-5011
Phone : 301-619-4721
Fax : 301-619-2492
Email : david.norwood@amedd.army.mil

Each Federal Partner may designate new liaisons at any time by notifying the other Partner's administrative liaison in writing. If at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Federal Partner will name a new liaison within 2 weeks and notify the other Partner through the designated administrative liaison.

TERM, TERMINATION AND MODIFICATION

This MOU shall be effective upon the date of the last signatory to the MOU and will automatically expire five (5) years from effective date unless written notice is given and there is and mutual agreement between the Federal Partners to revise it. This MOU may be terminated by either party by giving at least 60 days advance written notice. This MOU may be terminated by either party immediately upon written notice in the event that a Federal statute is enacted or regulations are issued by either Federal Partner that materially affects this MOU. This MOU may be amended at any time upon mutual consent of the parties.

FDA Record No. 225-08-6000

SIGNATURES OF RESPONSIBLE PARTIES

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 9/5/08
Signature of authorized representative Date

FRANK M. TORTI, MD, MPH
Principal Deputy Commissioner and Chief Scientist
U.S Food and Drug Administration

UNITED STATES ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES

BY: _____ 27 Aug 08
Signature of authorized representative Date

John P. Skvorak
Colonel, US Army
Commanding
U.S. Army Medical Research Institute of Infectious Diseases

[FR Doc. E8–25740 Filed 10–29–08; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: November 19, 2008, 8:30 a.m.–5 p.m. November 20, 2008, 8:30 a.m.–2:30 p.m.

Place: The Legacy Hotel and Meeting Centre, 1775 Rockville Pike, Rockville, Maryland 20852, Telephone: 301–881–2300.

Status: The meeting will be open to the public.

Agenda: On the morning of November 19, following the welcoming remarks from the COGME Chair and the Executive Secretary of COGME, there will be a panel discussion of the International Physician Workforce Conference held in Scotland, followed by (1) a presentation on the GAO Study Initiative on trends in Medical Residencies and Specialty choice and (2) a StudyInitiative on Primary Care Projections. In the afternoon there will be an update of Modeling and Analysis for Determining Supply of and Demand for Residency Positions by Specialty. There will be breakouts of Council members into two task groups.

On November 20, there will be reports of the two task groups and further discussion on Variables and Scenarios for modeling the impact on physician specialty distribution.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–4443.

Dated: October 23, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–25775 Filed 10–28–08; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings 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