The sources of the previous data are records of generic drug applications over the past 10 years.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: October 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25741 Filed 10–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]
[FDA No. 225–07–1000]

Memorandum of Understanding With the National Heart, Lung, and Blood Institute, a Part of the National Institutes of Health

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's Center for Biologics Evaluation and Research (CBER) and the National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH). This MOU outlines the terms of collaboration between CBER and NHLBI in areas of mutual concern for protecting and improving the public health. Specifically this MOU provides for the implementation of a plan for promoting better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for discussion of scientific and clinical topics, questions, and problems that may arise. This MOU also provides the framework for sharing of information.

DATES: The agreement became effective September 11, 2008.

FOR FURTHER INFORMATION CONTACT: Keith Wonnacott, Cellular Therapy Branch (HFM–720), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5102; or John W. Thomas, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute MSC 7950, 6701 Rockledge Dr., Rockledge II, rm. 9150, Bethesda, MD 20892–7950, 301–435–0065.

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.

BILLING CODE 4160–01–S

FDA MOU No. 225-07-1000

MEMORANDUM OF UNDERSTANDING FOR SHARING OF NON-PUBLIC INFORMATION
between the
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
and the
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

I. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) and the National Institutes of Health/National Heart, Lung, and Blood Institute (NIH/NHLBI) provides a framework for coordination and collaborative efforts between these two parties, which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information sharing between FDA/CBER and NIH/NHLBI will take place.

II. BACKGROUND

FDA and NIH are agencies within the Department of Health and Human Services (DHHS). Both FDA and NIH exist and work to protect the public health but have different statutory mandates and responsibilities.

FDA is a science-based regulatory agency responsible for protecting the public health through the regulation of food, cosmetics, radiation-emitting devices, and medical products, including human drugs, biological products, animal drugs, and medical devices. FDA administers the Federal Food, Drug, and Cosmetic Act and relevant sections of the Public Health Service Act, among other statutes. Among its duties, FDA reviews and monitors the use of investigative articles in clinical studies, conducts on-site inspections of biomedical research, approves pre-market applications, conducts regulatory research, conducts inspections of manufacturing facilities, and monitors post-marketing adverse events. FDA also refers civil and criminal cases to the Department of Justice to enforce applicable laws and regulations. Within FDA, CBER's mission is to protect and enhance the public health through regulation of biological and related products including blood, vaccines, human cells, tissues, or cellular or tissue-based products, allergenics, and many combination products according to statutory authorities in Sections 351 and 361 of the Public Health Service Act and in specific sections of the Federal Food, Drug, and Cosmetic Act. The regulation of these products is founded on science and law to ensure their safety, purity, and potency, including effectiveness.

The NIH is the Federal focal point for biomedical research in the United States. The NIH mission is to uncover new knowledge that will lead to better health for everyone. The NIH works toward that mission by conducting research in its own laboratories; supporting the

research of non-Federal scientists in universities, medical schools, hospitals and research institutions throughout the country and abroad; helping in the training of research investigators; and fostering communication of medical information. Within the NIH, the NHLBI, a component of the NIH, is the nation's leading supporter of biomedical research on disorders of the heart, lung, and blood systems and the mission of the NHLBI is to reduce the burden of disease in this areas. To achieve its mission of reducing the public health burden associated with heart, lung, and blood diseases, the NHLBI conducts, fosters, coordinates, and guides research on the causes, prevention, diagnosis, and treatment of heart, vascular, lung, blood, and sleep disorders, including basic research in related scientific areas.

The missions of FDA and the NIH are complementary and may overlap depending upon the subject matter. The agencies work collaboratively to protect and improve public health. There are occasions when FDA/CBER or NIH/NHLBI may have information that could be useful to the other party in that party's performance of its responsibilities. Timely sharing of information between FDA/CBER and NIH/NHLBI may often be critical to protecting and improving the public health.

III. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

A. Coordination and Collaboration Relative to Public Health Activities

It is mutually agreed that, on an as needed basis and as resources permit:

1. FDA/CBER and NIH/NHLBI will coordinate and collaborate with each other to protect and improve the public health. Each party will utilize the expertise, resources, and relationships of the other in order to increase its own capability and responsiveness, but all activities under this MOU are subject to the availability of personnel, resources, and appropriated funds. In addition, each party will designate central contact points[1] to coordinate communications from the other concerning matters covered by this agreement.

2. Each party will participate in periodic meetings to promote better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for discussion of scientific and clinical topics, questions and problems that may arise.

3. Each party may notify the other when important issues of mutual concern regarding the public health become evident to the extent such notification does not interfere with the public health, oversight, enforcement, or compliance responsibilities of the notifying agency.

[1] See section V. of this MOU.

4. The parties will work together to create an Implementation Work Plan. This Implementation Work Plan will itemize specific projects and activities that constitute the substance of the collaborative arrangement between the two agencies, and is intended to serve as a general working plan for each Office within FDA/CBER and NIH/NHLBI program areas to use in carrying out this agreement. The parties will follow the principles and procedures set forth in this MOU when creating and carrying out the Implementation Work Plan.

5. This agreement does not preclude FDA/CBER or NIH/NHLBI from entering into other agreements that may enable special programs to be handled more efficiently and expertly.

B. Principles and Procedures for the Sharing of Non-Public Information

FDA/CBER and NIH/NHLBI agree that the following principles and procedures will govern the sharing of non-public information, as resources permit, between the two parties.

Although there is no legal requirement that FDA/CBER and NIH/NHLBI exchange information in all areas, FDA/CBER and NIH/NHLBI agree that there should be a presumption in favor of full and free sharing of information between FDA/CBER and NIH/NHLBI. As public health agencies within DHHS, there are no legal prohibitions that preclude FDA or the NIH from sharing with each other most information in the possession of either agency. Both parties recognize and acknowledge, however, that all non-public information shared between FDA/CBER and NIH/NHLBI, whether written or oral, must be protected from any disclosure not authorized by law or regulation. See e.g., 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 CFR Parts 20 and 21; 42 U.S.C. § 241(d); 45 CFR Parts 5 and 5b. Safeguards are needed to protect shared non-public information, both written and oral, such as trade secrets and confidential commercial information; identities of study participants and other personal privacy information; privileged and/or pre-decisional agency information; research proposals, progress reports, and/or unpublished data; or national security information. Such safeguards also help ensure FDA/CBER's and NIH/NHLBI's compliance with other applicable laws and regulations.

To facilitate the sharing of non-public information, whether written or oral, FDA/CBER and NIH/NHLBI will implement procedures to ensure that such sharing is appropriate and that the recipient party will guard the confidentiality of all information received.[2] Both parties are committed to responding to requests for information in a complete and timely manner, consistent with budgetary and resource constraints, and to the extent permitted by law, regulation, and agency policy and practice. The party receiving shared non-public

[2] Each party has implemented or will implement the agency's data and information security statutory, regulatory, policy, or procedural requirements and has implemented or will implement, to the extent necessary and practicable, all data and information security recommendations suggested by the other agency.

information (requesting party), whether written or oral, will be responsible for protecting that information from any unauthorized disclosure. Provisions for sharing of non-public information, both written and oral, in accordance with applicable statutes or regulations are set out below:

1. The requesting party must specify, in writing,[3] the information requested (to facilitate identification of relevant information), provide a brief statement of why the information is needed, and include the following requesting party template language: "This request is made pursuant to the Memorandum of Understanding for Sharing of Non-Public Information between FDA/CBER and NIH/NHLBI, dated [insert date agreement was signed]. [Requesting party] agrees not to disclose any non-public information shared between FDA/CBER and NIH/NHLBI whether orally or in writing, in any manner." This request will state which internal unit offices and/or individuals are requesting the information.

2. The party receiving the request (sharing party) will determine, based upon the request described in section III.B.1 above, whether it is appropriate and practicable to share the requested non-public information.

3. The requesting party will comply with the following conditions:

   a. The requesting party will limit the dissemination of shared non-public information it receives to internal unit offices and/or employees that have been identified in its written request. The unit official who signs the request letter will be responsible for ensuring that there are no inappropriate recipients of the information.

   b. The requesting party will agree in writing not to disclose any shared non-public information in any manner not authorized by law or regulation, including disclosure in publications and public meetings, or in the context of other agency collaborations. If the requesting party wishes to disclose shared information that the sharing party has designated as non-public, the requesting party will ask the sharing party whether the information's non-public status has changed, and if so, will first obtain written confirmation and permission from the sharing party before disclosing that information. If the requesting party receives a Freedom of Information Act (FOIA) request for shared information, the requesting party will: (a) refer the FOIA request to the information-sharing contact person or designee for the sharing party to respond directly to the FOIA requester regarding the releaseability of the information, and (b) notify the FOIA requester of the referral and that a response will issue directly from the sharing party. The requesting party will leave all final disclosure decisions up to the sharing party, including decisions on whether the records are responsive and whether they must be disclosed. Accordingly, the requesting party will not indicate to the FOIA

[3] The term "writing" used throughout this MOU includes a writing by electronic means.

requester whether the sharing party has responsive records or releaseable records. The sharing party will include a response in writing along with any agency information shared. The response will indicate the type of information (e.g., confidential commercial information, personal privacy, pre-decisional, etc.), and will include the following sharing party template language: "Pursuant to the Memorandum of Understanding for Sharing of Non-Public Information between the FDA/CBER and the NIH/NHLBI, dated [insert date agreement was signed], the non-public information provided in this communication may not be disclosed or shared in any manner." Any shared documents containing non-public information should be stamped "***Do not disclose or further distribute.***"

c. The requesting party will promptly notify the contact person or designee of the sharing party of any attempt by a third party to obtain shared non-public information by compulsory process, including, but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

d. The requesting party will notify the sharing party before complying with any judicial order that compels the release of shared non-public information, so that the parties may determine the appropriate measures to take, including, where appropriate, legal action.

IV. NAME AND ADDRESS OF PARTICIPATING PARTIES

Food and Drug Administration
Center for Biologics Evaluation and Research
29 Lincoln Drive (HFM-1)
Bethesda, MD 20892-4555
Telephone: (301) 827-0548
Fax: (301) 827-0440

National Institutes of Health
National Heart, Lung, and Blood Institute
Building 31, Room 5A48
31 Center Drive MSC 2486
Telephone: (301) 496-5166
Fax: (301) 402-0818

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V. LIAISON OFFICERS

Liaison Officers will participate in the management, coordination and oversight of this agreement. The Liaison Officers will constitute a Steering Committee consisting of an equal number of member representatives from FDA/CBER and NIH/NHLBI. Two Liaison Officers, one designate from each participating agency, will serve as co-chairs of the Committee.

Member appointments will be authorized by the signatories to this agreement. The Liaison Officer Steering Committee will meet at least once every six months for the first year of this agreement and then at least once annually thereafter to review the progress of this agreement, resolve any issues and disputes that may arise, and oversee necessary modifications to the agreement.

A. For FDA/CBER

Keith Wonnacott, Ph.D.
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Office of Cellular, Tissue and Gene Therapies
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US Food and Drug Administration
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Fax: (301) 827-9796
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Kimberly Benton, Ph.D.
Deputy Director, Division of Cell and Gene Therapy
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
US Food and Drug Administration
Division of Cell and Gene Therapies
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B. For NIH/NHLBI

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Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
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Rockledge II, Room 9150
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Carol J. Blaisdell, M.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, MSC 7952
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Telephone: (301) 435-0222
E-mail: blaisdellcj@nhlbi.nih.gov

Denis Buxton, Ph.D.
Division of Cardiovascular Diseases
National Heart, Lung, and Blood Institute
Rockledge II, Room 8216
6701 Rockledge Drive, Mail Stop 8902
Bethesda, MD 20892-8902
Telephone: (301) 435-0513
E-mail: buxtond@nhlbi.nih.gov

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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: _____

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: _____

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.