Dated: March 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5494 Filed 3–12–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2009–N–0667]
[FDA 225–07–8006]

Memorandum of Understanding With Baylor College of Medicine, The University of Texas M.D. Anderson Cancer Center, Rice University, University of Houston, The University of Texas Health Science Center at Houston, Texas A&M Health Science Center, The University of Texas Medical Branch at Galveston, and The Methodist Hospital Research Institute for the FDA-ANH Nanotechnology Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) with The Alliance for NanoHealth (ANH), a collaboration among: Baylor College of Medicine, The University of Texas M.D. Anderson Cancer Center, Rice University, University of Houston, The University of Texas Health Science Center at Houston, Texas A&M Health Science Center, The University of Texas Medical Branch at Galveston, and The Methodist Hospital Research Institute. This MOU identifies the terms of collaboration between FDA and ANH in the area of nanotechnology. Specifically, this MOU establishes the FDA-ANH Nanotechnology Initiative (FANTI), a public-private partnership dedicated to the identification of scientific and translational gaps in moving nanoengineered medical products from the preclinical stages of development through clinical stages and then to commercialization, all with immediate benefit to public health. The activities are aligned with the mutual interests and respective missions of the Parties, including the FDA's Critical Path Initiative which seeks to modernize the product development and regulatory sciences needed to reduce uncertainties about product performance throughout the product life cycle. Thus, a key goal for the Parties is to improve the safety and efficacy of nanoengineered products and speed their delivery to the patients who need them and the consumers who use them.

DATES: The agreement became effective February 11, 2009.

FOR FURTHER INFORMATION CONTACT: Wendy R. Sanhai, Office of the Commissioner (HZ–1), Food and Drug Administration, 5600 Fishers Lane, suite 6A–08, Rockville, MD 20857, 301–827–7867.

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: March 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

BILLING CODE 4160–01–S

MOU# 225-07-8006

MEMORANDUM OF UNDERSTANDING BY AND AMONG THE

UNITED STATES FOOD AND DRUG ADMINISTRATION

BAYLOR COLLEGE OF MEDICINE

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

RICE UNIVERSITY

UNIVERSITY OF HOUSTON

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

TEXAS A&M HEALTH SCIENCE CENTER

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

THE METHODIST HOSPITAL RESEARCH INSTITUTE

FOR THE

FDA-ANH NANOTECHNOLOGY INITIATIVE

MOU# 225-07-8006

This Memorandum of Understanding (MOU) is executed by and among the United States Food and Drug Administration (FDA), Baylor College of Medicine (BCM), William Marsh Rice University (Rice), University of Houston (UH), The University of Texas M. D. Anderson Cancer Center (UTMDACC), The University of Texas Medical Branch at Galveston (UTMB), The University of Texas Health Science Center at Houston (UTHSCH), Texas A & M Health Science Center (Texas A&M) and The Methodist Hospital Research Institute (TMHRI), hereafter referred to individually as a "Party" and collectively as the "Parties." This MOU is deemed effective on the date of the last Party to sign (Effective Date).

WHEREAS, each Party has unique expertise in certain areas of nanotechnology, regulatory science, and other areas of translational, health related and clinical sciences; and

WHEREAS, the Parties wish to leverage their expertise and resources for the purposes of stimulating innovation in the field of nanotechnology and working collaboratively to bridge scientific gaps and to develop evaluative and predictive tools to facilitate the development of nanoengineered medical products in the interest of public health; and

WHEREAS, the Parties recognize the existence of a collaboration among the eight (8) academic institutions represented in this MOU called the Alliance for NanoHealth (ANH) which functions under the terms and conditions of the Alliance for NanoHealth Operating Agreement. The ANH will serve to facilitate and coordinate the activities contemplated hereunder,

NOW, THEREFORE, in consideration of the mutual agreement of the Parties hereto, and of the covenants and conditions hereinafter expressed, the Parties hereby agree as follows:

I. PURPOSE

The Parties will work with multiple organizations, facilitated and coordinated through the ANH, to identify scientific and translational gaps in moving nanoengineered medical products from the preclinical stages of development through clinical stages and then to commercialization, all with immediate benefit to public health. The activities described herein are aligned with the mutual interests and respective missions of the Parties, including the FDA's Critical Path Initiative which seeks to modernize the product development and regulatory sciences needed to reduce uncertainties about product performance throughout the product life cycle. Thus, a key goal for the Parties is to improve the safety and efficacy of nanoengineered products and speed their delivery to the patients who need them and the consumers who use them.

II. BACKGROUND

The FDA's mission is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is interested in understanding the risks and benefits of nano-engineered medical product development to the extent that this information can facilitate the regulatory review and evaluation of new medical products that incorporate nanotechnology.

The ANH was created out of a unique multi-disciplinary, multi-institutional collaborative research endeavor linking eight (8) academic and clinical institutions in the Greater Houston region with an aim of leveraging their resources and technical expertise in nanotechnology to bridge the gaps between medicine, biology, materials science, computer technology, and public policy.

The Parties have expressed a willingness to leverage their combined strengths among the scientific disciplines, with goals in applied research, educational, and training activities. The Parties are committed to developing and applying nanotechnology tools in the battle against multiple diseases and in the development of cross-cutting technologies.

III. PARTICIPATION OF PARTIES

The Parties agree to the following, to be developed and pursued through separate written agreements as needed:

1. To form a subcommittee of the ANH made up of representatives of the Parties and other key stakeholders to: (a) recommend program and funding priorities, implement programs, and oversee the activities to fulfill the purpose of this MOU as set forth in Paragraph I above; and (b) to form task/program/project-specific working groups, as needed, to develop strategic program plans, establish project selection criteria, develop feasible funding and implementation plans for programs/projects, including leveraging resources and expertise from multiple sources including the private sector, academia, professional organizations and others.

2. To share information and data, to the extent permitted by protocol and by State and Federal law, and provide access to best practices and know-how produced from activities under this MOU, in a timely manner and as appropriate. Such shared information may, if deemed permissible under applicable State and Federal statutes, include assessment tools for use during the FDA's regulatory evaluation and during guidance development to facilitate medical product development, characterization approaches, and best practices to: (a) support understanding and resolution of potential implications of nanotechnology-based products for clinical application; (b) facilitate the development of measurement methods and standard protocols appropriate to innovative technologies; and (c) facilitate transfer of science and engineering discovery and development to the clinic through careful linkage with the measurement science and standard programs and regulatory science and policy development.

3. To develop and implement separate programs and agreements, within the framework of this MOU and to the extent time, resources, and applicable State and Federal statutory and regulatory requirements permit, to allow:

    a. Development and refinement of the preclinical and early clinical pathway(s) for nanotechnology-based drugs, biologics, devices and combination products to guide technology development leading to medical products;

b. Development and validation of standards, risk/benefit analyses and other evaluative tools to identify risks and assess safety and efficacy in newly emerging nanoengineered products;

c. Generation of data and best practices that will be publicly available e.g. protocols, assay cascades, and other pre-competitive tools developed collaboratively by the Parties, and that may guide further advancement in the field of nanotechnology;

d. Development, validation, and assessment of assays and other appropriate test methods, with close review and input from all Parties prior to standardization and validation of said assays;

e. Development of joint translational research programs that also support academic scientists, trainees and scientific fellows identified under joint training programs, and under the FDA's Critical Path Initiative, to perform research at the respective facilities of the Parties and in collaboration with respective scientists and staff comprising the Parties, as well as potential research collaborations with other organizations; and

f. Representation for each Party at jointly held meetings and other scientific conferences, as applicable and appropriate.

4. To serve as an infrastructure for fostering additional concepts or ideas involving joint projects or integrated approaches to science or technology development specifically aimed at developing nanoengineered products. To achieve this goal, and as permissible by State and Federal law, designated representatives from the Parties will meet at least quarterly to review progress and address new opportunities for collaboration and associated sources of funding. Such opportunities will be formally presented to the ANH for approval and implementation. As needed and as permitted by State and Federal law, technical and programmatic advisory working groups made up of employees from the respective Parties may be assembled to make formal recommendations for collaboration. Any individual project(s), group(s), or committees established pursuant to this MOU shall be defined in separate written agreements which will also outline procedures and processes for such project(s), group(s) or committees. Any such separate agreements must be approved in writing by authorized representatives of each of the parties involved. Any separate written agreement must be in compliance with all applicable State and Federal law, and FDA shall ensure its participation in any such separate agreements is permissible under applicable statutory and regulatory requirements. Such agreements shall set forth at a minimum, the scope of work; tasks, deliverables (if any) and delivery dates; anticipated products and outcomes; periods of performance; and any other appropriate and necessary aspects of project(s).

5. In addition to the activities set forth herein, the Parties may, as resources and State and Federal law permit, collectively develop and validate standards, nomenclature, assessment tools, and toxicology approaches to facilitate and accelerate the development of, and the evidence base for, new diagnostics and medical products that incorporate nanotechnology. The Parties may also develop educational programs and tools, and publications to make information and data generated widely available to patients, clinicians, and researchers. Any such activities, if deemed permissible under applicable

State and Federal statutes and regulations, shall be developed under, and governed by, separate written agreements signed by the Parties.

IV. RESOURCES

Sources of support for projects under this MOU will be governed by State and Federal law and applicable policies and procedures. The terms for such support will be set forth in the specific written agreements for each project.

V. GENERAL PROVISIONS

1. Nothing in this MOU alters the statutory authorities or obligations of FDA. This MOU is intended to facilitate cooperative efforts among the Parties in the area of nanotechnology.

2. U.S. Federal law and to the extent applicable the laws of the State of Texas govern this MOU for all purposes, including, but not limited to, determining the validity of the MOU, the meaning of its provisions, and the rights, obligations, and remedies of the Parties.

3. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate, separate, written Confidentiality Disclosure Agreements (CDAs), and to the extent such disclosure is permitted by State and Federal law.

4. It is understood that, although the Parties have mutual interests, there may be opportunities for independent collaborations and activities outside the scope of this MOU, but which are within the scope of the Parties' respective missions. As such, the Parties may, as appropriate, enter into independent negotiations and agreements with prospective partner/s without any effect on this MOU.

5. Materials and data being analyzed/studied under the terms and conditions of this MOU may be shared among the Parties only if permitted by applicable State and Federal law and any such sharing of materials and data will be governed by separate written Material and Data Transfer Agreements (MDTA). Parties will ensure that their participation in any MDTA is appropriate and permissible under applicable State and Federal law.

6. Rights to inventions or intellectual property developed will be addressed in separate written development and implementation agreements among the Parties. To the extent there is FDA participation in any projects related to development of any product, invention or property developed, such activities will be governed by applicable Federal law. This MOU does not license or convey any intellectual property or inventions owned or managed by any of the Parties to any other Party or to the ANH.

7. Any notice or other communication required or permitted under this MOU shall be in writing and will be deemed effective on the date it is received by the receiving Party.

8. FDA participation in this MOU is governed by Federal statutes and regulations.

VI. TERM, TERMINATION AND MODIFICATIONS

1. This MOU constitutes the entire agreement among the Parties and to the matters herein. There are no representations, warranties, agreements, or understandings, expressed or implied, written or oral, among the Parties relating to the subject matter of this MOU that are not fully expressed herein.

2. This MOU may be modified only upon the mutual written consent of all Parties. Modifications must be signed by the original signatories to this MOU, or by their designees or successors. No oral statement by any person shall be interpreted as modifying or otherwise affecting the terms of this MOU.

3. This MOU, when accepted by the Parties, will remain in effect for three (3) calendar years from the Effective Date, unless modified or terminated.

4. Any Party to this MOU may terminate its participation by written notice by at any time, with or without cause, and without incurring any liability or obligation. Such written notice shall be given by the terminating Party to the other Parties at least 60 days prior to the date of actual termination.

VIII. CONTACTS

Notices or formal communications pursuant to this MOU shall be sent in writing by personal delivery, overnight delivery, facsimile telecommunication with confirmatory receipt, or certified or registered mail, return receipt requested, to the following contact for each Party:

For FDA:
Wendy R. Sanhai, Ph.D.
Senior Scientific Advisor
Office of the Commissioner, FDA
5600 Fishers Lane, Suite 14 B-45, HZ-1
Rockville, MD. 20857
Phone: (301) 827-7867, Fax: (301) 827-5891
Email: wendy.sanhai@fda.hhs.gov

With a copy to:
Chekesha S. Clingman, Ph.D.
LCDR, USPHS
Senior Scientific Program Manager
Office of the Commissioner, FDA
5600 Fishers Lane, Suite 6A-08
Rockville, MD 20857
Phone: (301) 827-4044, Fax: (301) 827-5891
Email: chekesha.clingman@fda.hhs.gov

MOU# 225-07-8006

For ANH:	Mauro Ferrari, Ph.D. President, Alliance for NanoHealth 1825 Pressler, Suite 537D Houston, TX 77031 Phone: (713) 500-2444, Fax: (713) 500-2462 Email: mauro.ferrari@uth.tmc.edu
For BCM:	William T. Butler, M.D. Interim President, Baylor College of Medicine One Baylor Plaza Houston, Texas 77030 Fax Number: (713) 798-8811
With a copy to:	Office of General Counsel Baylor College of Medicine One Baylor Plaza, Room 106A Houston, Texas 77030 Fax Number: (713) 798-6368
For Rice:	David W. Leebron President, Rice University 6100 Main Street, MS-l Houston, Texas 77005 Fax Number (713) 348-5271
With a copy to:	Office of General Counsel Rice University 6100MainStreet, MS-94 Houston, Texas 77005 Fax Number (713) 348-5464
For Texas A&M:	Nancy W. Dickey, M.D. President, Texas A & M Health Science Center John B. Connally Building, 7th Floor 301 Tarrow College Station, Texas 77840-7896 Fax No. (979) 458-7202
With a copy to:	Chief Legal Officer Texas A & M Health Science Center John B. Connally Building, 7th Floor 301 Tarrow College Station, Texas 77840-7896 Fax No. (979) 458-7202

MOU# 225-07-8006

For UH:	Dr. Renu Khator Chancellor, UH System President, University of Houston 212 E. Cullen Building Houston, Texas 77204-2018 713-743-8820 713-743-8837 (fax)
With a copy to:	Vice Chancellor for Legal Affairs, UH System Vice President for Legal Affairs, UH General Counsel, UH System/UH 311 E. Cullen Building Houston, Texas 77204-2028 Phone: (713) 743-0949 Fax: (713) 743-0948
For UTMDACC:	John Mendelsohn, M.D. President, University of Texas M. D. Anderson Cancer Center 1515 Holcombe Blvd., Box 91 Houston, Texas 77030 Fax Number: (713) 799-2210
With a copy to:	Senior Vice President for Administrative Services and Chief Legal Officer The University of Texas M. D. Anderson Cancer Center 1515 Holcombe Boulevard, Box 537 Houston, Texas 77030 Fax Number: (713) 799-8801
For UTMB:	David L. Callender, M.D. President, University of Texas Medical Branch at Galveston 301 University Blvd. Galveston, Texas 77555-0129 Fax Number: (409) 772-5064
With a copy to:	Department of Legal Affairs 301 University Blvd. Galveston, Texas 77555-0124 Fax Number (409) 772-6049

MOU# 225-07-8006

For UTHSCH:	Larry R. Kaiser, M.D. President, The University of Texas Health Science Center at Houston 7000 Fannin, Suite 1700 Houston, Texas 77030 Fax Number (713) 500-3026
With a copy to:	Office of Legal Affairs The University of Texas Health Science Center at Houston 7000 Fannin Street, Suite 1460 Houston, Texas 77030 Fax Number: (713) 500-3275
For TMHRI:	Michael W. Lieberman, M.D., Ph.D. President & CEO The Methodist Hospital Research Institute 6565 Fannin Street, B490 Houston, Texas 77030 Fax Number: (713) 441-3886
With a copy to:	Vice President, Legal Services The Methodist Hospital System 6565 Fannin Street, D200 Houston, Texas 77030 Fax Number: (713) 793-7092

The Parties shall notify each other of any change of address or change of named contact by written notice. All notices shall be effective upon date of receipt.

Signatures begin on next page

MOU# 225-07-8006

SIGNATURES OF RESPONSIBLE PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION

Date 2/11/09

Frank M. Torti, M.D.
Principal ~~Deputy Commissioner and Chief~~ Scientist Acting Commissioner
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE BAYLOR COLLEGE OF MEDICINE

Date 1/9/09

APPROVED
Office of the General Counsel
Baylor College of Medicine
By LB 1/6/09

William T. Butler, M.D.
Interim President, Baylor College of Medicine

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

Date _____

Larry R. Kaiser, M.D.
President, The University of Texas Health Science Center at Houston

MOU# 225-07-8006

SIGNATURES OF RESPONSIBLE PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION

_____ Date _____

Frank M. Torti, M.D.
~~Principal Deputy Commissioner and Chief Scientist~~ Acting Commissioner
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE BAYLOR COLLEGE OF MEDICINE

_____ Date _____

William T. Butler, M.D.
Interim President, Baylor College of Medicine

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

_____ Date 12/12/08

Larry R. Kaiser, M.D.
President, The University of Texas Health Science Center at Houston

MOU# 225-07-8006

APPROVED AND ACCEPTED FOR WILLIAM MARSH RICE UNIVERSITY

David W. Leebron Date Jan. 16, 2009

David W. Leebron
President, Rice University

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

_____ Date_____

John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

_____ Date_____

Renu Khator, Ph.D.
President, University of Houston

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

_____ Date_____

David L. Callender, M.D.
President, The University of Texas Medical
Branch at Galveston

MOU# 225-07-8006

APPROVED AND ACCEPTED FOR WILLIAM MARSH RICE UNIVERSITY

_____ Date _____

David W. Leebron
President, Rice University

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

_____ Date 1/5/09

John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center

Reviewed and Approved by
UTMDACC Legal Services for
UTMDACC Signature:
12-18-08

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

_____ Date _____

Renu Khator, Ph.D.
President, University of Houston

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

_____ Date _____

David L. Callender, M.D.
President, The University of Texas Medical
Branch at Galveston

MOU# 225-07-8006

APPROVED AND ACCEPTED FOR WILLIAM MARSH RICE UNIVERSITY

_____ Date _____

David W. Leebron
President, Rice University

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

_____ Date_____

John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

dhc Renu Khator Date_____

Renu Khator, Ph.D.
President, University of Houston

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

_____ Date_____

David L. Callender, M.D.
President, The University of Texas Medical Branch at Galveston

MOU# 225-07-8006

APPROVED AND ACCEPTED FOR WILLIAM MARSH RICE UNIVERSITY

_____ Date _____

David W. Leebron
President, Rice University

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

_____ Date_____

John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

_____ Date_____

Renu Khator, Ph.D.
President, University of Houston

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

_____ Date DEC 19 2008

David L. Callender, M.D.
President, The University of Texas Medical Branch at Galveston

Content reviewed
MAE

MOU# 225-07-8006

APPROVED AND ACCEPTED FOR TEXAS A&M HEALTH SCIENCE CENTER

Nancy W Dickey MD Date 1/20/09

Nancy W. Dickey, M.D.
President, Texas A&M Health Science Center

APPROVED AND ACCEPTED FOR THE METHODIST HOSPITAL RESEARCH INSTITUTE

_____ Date_____

Michael W. Lieberman, M.D., Ph.D.
President & CEO, The Methodist Hospital
Research Institute

MOU# 225-07-8006

APPROVED AND ACCEPTED FOR TEXAS A&M HEALTH SCIENCE CENTER

_____ Date_____

Nancy W. Dickey, M.D.
President, Texas A&M Health Science Center

APPROVED AND ACCEPTED FOR THE METHODIST HOSPITAL RESEARCH INSTITUTE

MD Date 12/12/08

Michael W. Lieberman, M.D., Ph.D.
President & CEO, The Methodist Hospital
Research Institute

APPROVED AS TO FORM
By
TMH Legal Services

[FR Doc. E9–5492 Filed 3–12–09; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Clinical Trials Endpoints for Acute Graft-Versus-Host Disease After Allogeneic Hematopoietic Stem Cell Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) and National Institutes of Health (NIH) in co-sponsorship with the Center for International Blood and Marrow Transplantation Research (CIBMTR) and the American Society for Blood and Marrow Transplantation (ASBMT) are announcing a public workshop entitled ''Clinical Trials Endpoints for Acute Graft-Versus-Host Disease (GVHD) After Allogeneic Hematopoietic Stem Cell Transplantation.'' This is a 1-day workshop for academics, government researchers, clinical trial experts, government regulators, and industry representatives. The purpose of the public workshop is to review the data that will serve as the foundation for protocol design and clinical trial evidence-based endpoints intended to support the approval of new drugs or biologics to prevent or treat acute GVHD. The public workshop also will inform FDA and assist investigators in facilitating clinical development programs for products to prevent or treat acute GVHD indications.

Date and Time: The public workshop will be held on May 19, 2009, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Hilton Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Overnight accommodations can be booked at the Hilton under group code ''MCW'' for the conference rate by calling 1–800–445–8667 or by using the Reservation Web site at*http://www.hilton.com/en/hi/groups/personalized/IADMRHF–MCW–20090518/index.jhtml*. Accommodation agreement courtesy of CIBMTR. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

Contact Person: Leslie Haynes, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079; e-mail: *CBERTraining@fda.hhs.gov* (Subject line: Acute GVHD Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the Contact Person by April 18, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8:15 a.m.

If you need special accommodations due to a disability, please contact Leslie Haynes at least 7 days in advance.

SUPPLEMENTARY INFORMATION: At the present time, there are no drugs or biologics approved for prevention or treatment of acute GVHD. Development of products to prevent or treat acute GVHD poses several challenges. First, the market is not very big, so there is little incentive for investment if the process is cumbersome; second, analyses of these studies are complicated by confounding factors; and third, there is a lack of evidence-based endpoints that can be used to demonstrate a clinically meaningful benefit of any therapy.

The Center for Biologics Evaluation and Research is the FDA Center with regulatory responsibility for vaccines, blood and blood products, allergenic products, and therapies involving cells, tissues, and genes. The mission of FDA is to protect and enhance the public health including the safety and purity of medical products and the Nation's blood supply. The purpose of this event is to review the data that can be used to develop evidence-based endpoints for clinical trials targeting acute GVHD.

ASBMT is a professional organization that promotes advancement of the field of blood and bone marrow transplantation. Its members are both in clinical practice and in research.

CIBMTR is a research network comprised of the National Marrow Donor Program© and the International Bone Marrow Transplant Registry and Autologous Blood and Marrow Transplant Registry. Its activities include support for the National Heart, Lung and Blood Institute (NHLBI)-funded Blood and Marrow Transplantation Clinical Trials Network and Health Resources and Services Administration's C.W. Bill Young Cell Transplantation Program. The goals of the CIBMTR include defining key areas for future research in collaboration with leading scientists, physicians, and others in the blood and marrow transplant community; the design and implementation of clinical studies; and making available research resources including a clinical database of related blood and marrow transplants, along with repositories of matched tissue samples from transplant recipients and their donors.

The NHLBI, National Institute of Allergy and Infectious Diseases (NIAID), National Cancer Institute (NCI), and Office of Rare Diseases (ORD) are at the National Institutes of Health (NIH), the primary Federal agency for conducting and supporting medical research. NIH's mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

The public workshop will feature presentations by FDA, CIBMTR, and members of ASBMT. The topics to be discussed include the following: (1) Regulatory requirements for clinical trials, (2) extant data which support the endpoints currently used in clinical trials, (3) data analyses to support the validity of the proposed endpoints, (4) statistical approaches to minimize confounding factors in stem cell transplantation study analysis, (5) biomarkers for acute GVHD, and (6) patient-reported outcomes for acute GVHD prevention and treatment trials.

Presentations: Presentations from the public workshop will be maintained on the CIBMTR's Web site for at least 1 year.

Dated: March 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5496 Filed 3–12–09; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Women's Health Initiative Observational Study

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection