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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.

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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