

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

DPM

Strategies for Developing Therapeutics That Directly Target Anthrax and Its Toxins; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Strategies for Developing Therapeutics That Directly Target Anthrax and Its Toxins." The goals of the public workshop are to provide a forum for sharing information and discussing strategies for safety and efficacy testing of therapeutics that target anthrax and its toxins in order to expedite the development of these FDA-regulated products; and to address the optimal studies for product characterization, proof of concept, and demonstration of safety and efficacy in postexposure prophylaxis and/or in the treatment of established disease. The workshop will cover therapies that involve monoclonal antibodies, other recombinant proteins, polyclonal immune globulin (human or animal) and small molecules that inhibit toxins. The workshop will not cover the use of vaccines and antimicrobial drugs targeting anthrax and its toxins.

Date and Time: This 2-day public workshop will be held on June 10, 2004, from 8:30 a.m. to 5 p.m., and June 11, 2004, from 8:30 a.m. to 3 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), Natcher Auditorium, Bldg. 45, 45 Center Dr., Bethesda, MD

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The NIH campus is accessible via the Washington, DC Metro Transit System, Red Line, at the Medical Center Station. The Natcher Conference Center is a short walk from the metro station, or you may take a shuttle bus that runs from the metro station to the various buildings on the campus. Because of security measures, visitors' parking is extremely limited and use of private vehicles may cause significant delays in entering the campus. Additionally, you will be required to show a photo ID upon entry to the campus and the Natcher Conference Center.

Contact Person: Melanie Whelan, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-3841, FAX: 301-827-3079, e-mail: Whelan@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone number, e-mail address, and FAX number) to the contact person by Friday, May 21, 2004. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. There will be no onsite registration.

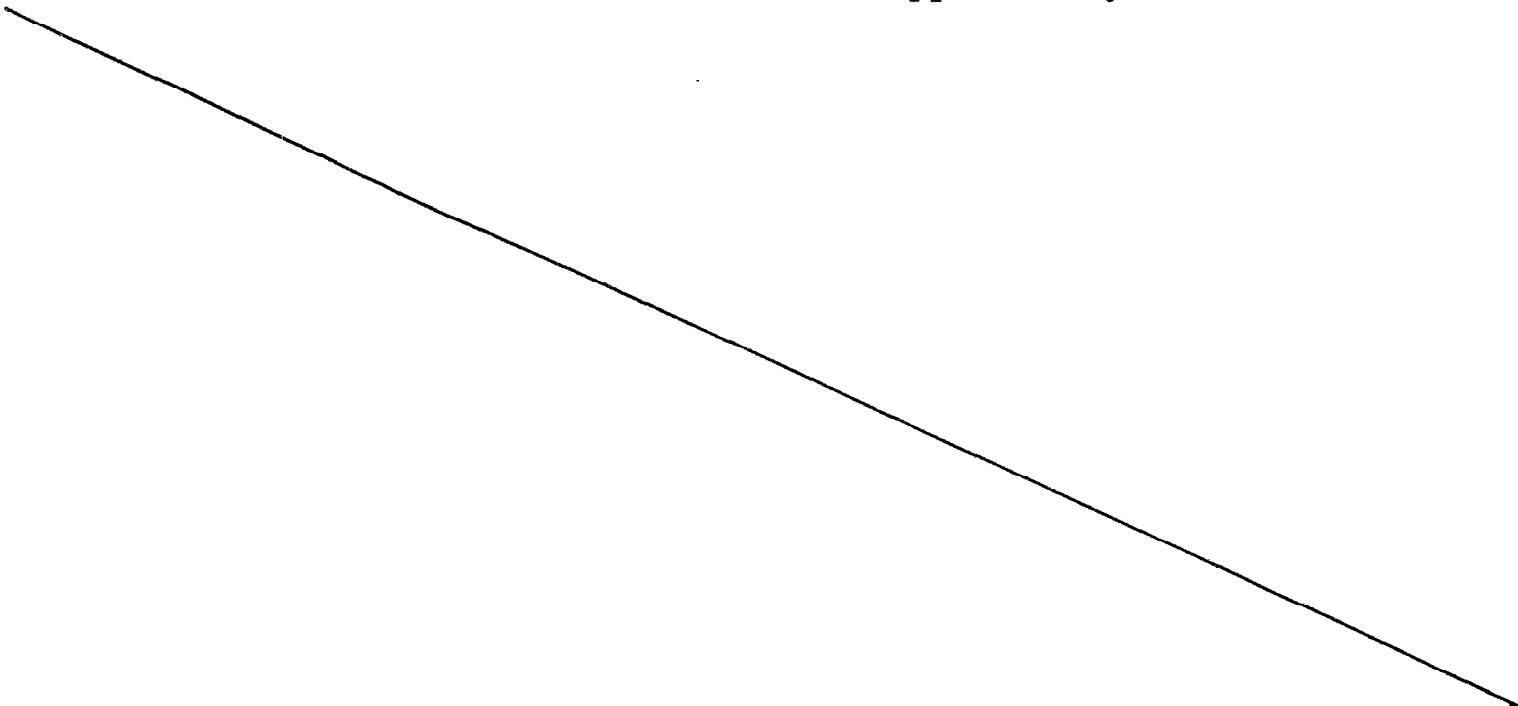
If you need special accommodations due to a disability, please contact Melanie Whelan (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research; the National Institutes of Health, National Institute of Allergy and Infectious Diseases; the Centers for Disease Control and Prevention; and the Department of Health and Human Services, Office of Research and Development Coordination are cosponsoring a public workshop. The public workshop will provide a forum for sharing information and discussing strategies for safety and efficacy testing of

therapeutics, including monoclonal antibody-based therapies, other recombinant proteins, polyclonal immune globulins (human and animal derived), and small molecules, that target anthrax and its toxins in order to expedite the development of these FDA-regulated products. The use of vaccines and antimicrobial drugs targeting anthrax and its toxins will not be covered. The public workshop is intended to address the optimal studies for product characterization, proof of concept, and demonstration of safety and efficacy in postexposure prophylaxis and/or in the treatment of established disease.

Mail or fax your issues and questions to Melanie Whelan (see *Contact Person*) by Friday, May 28, 2004. (There will be an opportunity to raise additional questions and issues for discussion at the public workshop.) The agenda for this public workshop, when finalized, will be posted on the Center for Biologics Evaluation and Research's Web site at <http://www.fda.gov/cber/scireg.htm>.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15



working days after the public workshop at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: 4/28/04
April 28, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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