

antihypertensive and lipid lowering treatment to prevent heart attack trial (ALLHAT).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 29, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 29, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact John Lautman at 301-827-7001 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 2, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05-4522 Filed 3-8-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure; 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: "Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure." The purpose of the workshop is to address current topics on the safety and efficacy of immune globulin products.

Date and Time: The workshop will be held on April 13, 2005, from 8 a.m. to 5:30 p.m.

Location: The workshop will be held at the Lister Hill Auditorium, Bldg. 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3514, FAX: 301-827-2843, e-mail: dawsonr@cber.fda.gov.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by April 1, 2005. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:15 a.m.

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

SUPPLEMENTARY INFORMATION: FDA, in cooperation with the Primary Immune Deficiency Foundation, is announcing the following public workshop: "Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure." The 1-day workshop, consisting of three successive sessions, will discuss the following topics:

- Specific antibody levels in intravenous immune globulins (IGIVs) to common and emerging pathogens, including research questions concerning antibody levels and efficacy;
- Adverse events, including specific categories of adverse events, as well as current methods of surveillance, responses to adverse event information, and the utility of different monitoring strategies; and
- Paradigms for IGIV and subcutaneous immune globulin licensure for treatment of Primary Immune Deficiency.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: March 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-4634 Filed 3-8-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1993D-0394]

Draft Guideline for the Validation of Blood Establishment Computer Systems; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance that was issued on September 28, 1993.

DATES: March 9, 2005.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION: In a notice containing a cumulative list of guidances available from the agency that published on January 5, 2005 (70 FR 824), FDA included the guidance document entitled, "Draft Guideline for the Validation of Blood Establishment Computer Systems." This document is being withdrawn because it no longer reflects all of FDA's current considerations on a guidance to assist manufacturers of blood and blood components, including blood banks, plasmapheresis centers, and transfusion services in developing a computerized system validation program. FDA is revising the guidance and a draft guidance for public comment will be issued in the future.

Dated: March 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-4633 Filed 3-8-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Commission on Systemic Interoperability, March 15,