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 Lauttman 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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4160–01–S

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,

2005, 8 a.m. to March 15, 2005, 4 p.m., Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, Washington, DC 20201, which was published in the **Federal Register** on February 4, 2005, 70 FR 6025.

The meeting location has changed to the National Library of Medicine, Building 38, 2nd Floor Mezzanine, Board Room, 8600 Rockville Pike, Bethesda, Maryland 20894. The meeting is open to the public.

Dated: March 2, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–4569 Filed 3–8–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Request for Public Comment on Draft Reports on Xenotransplantation

The Secretary's Advisory Committee on Xenotransplantation (SACX) is requesting public comment on two draft reports on xenotransplantation. One is on the state of the science of xenotransplantation and the other is on informed consent issues in clinical trials involving xenotransplantation.

Before the reports are finalized and transmitted to the Secretary, the SACX is requesting comments on the draft reports from members of the public. All public comments received will be considered in finalizing the reports. Comments should be submitted by March 31, 2005. Received comments will be available for public inspection at the NIH Office of Biotechnology Activities, Monday through Friday between the hours of 8:30 a.m. and 5 p.m., at the contact address noted below.

Information: The Secretary's Advisory Committee on Xenotransplantation, Department of Health and Human Services, considers the scientific, medical, social, and ethical issues and the public health concerns raised by xenotransplantation and makes recommendations to the Secretary on policy and procedures. The Committee's charges include advising on the current state of knowledge regarding xenotransplantation and on the potential for transmission of infectious diseases as a consequence of xenotransplantation; and deliberating on medical, public health, ethical, legal and socioeconomic issues, including international policies and developments that are relevant to xenotransplantation.

Overview of Drafts: The state of the science report addresses the scientific challenges in xenotransplantation, the infectious disease risks associated with xenotransplantation, public health concerns associated with xenotourism, knowledge gaps and resource limitations, and alternative strategies to xenotransplantation. The report also proposes a series of recommendations regarding these issues.

The report on informed consent issues in clinical research involving xenotransplantation addresses the ethical foundations and functions of informed consent, components of informed consent, the informed consent process, informed consent forms, and special issues raised by xenotransplantation. The report proposes a series of recommendations regarding informed consent in xenotransplantation research.

The full draft reports are available electronically at *http://www4.od.nih.gov/oba/Sacx.htm.* A paper or electronic copy can also be requested by calling the NIH Office of Biotechnology Activities at (301) 496–9838 or by e-mailing Mary Groesch at *groeschm@od.nih.gov.*

Contact Person: Mary Groesch, Ph.D., Executive Director, Secretary's Advisory Committee on Xenotransplantation, Office of Biotechnology Activities, Rockledge I, Room 750, Bethesda, MD 20892. (301) 496–9838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS.)

Dated: March 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–4568 Filed 3–8–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of the Styrene Expert Panel Meeting and Availability of the Draft Expert Panel Report on Styrene; Request for Public Comment on the Draft Report

AGENCY: National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Announcement of a meeting and request for comment.

SUMMARY: The CERHR announces the availability of the draft expert panel report for styrene on March 18, 2005, from the CERHR Web site *(http://cerhr.niehs.nih.gov)* or in printed text from the CERHR (*see* **FOR FURTHER INFORMATION CONTACT** below). The CERHR invites the submission of public comments on sections 1–4 of the draft expert panel report (see **SUPPLEMENTARY INFORMATION** below). The expert panel will meet on June 1–3, 2005, at the Holiday Inn Old Town Select in Alexandria, Virginia to review and revise the draft expert panel report and reach conclusions regarding whether exposure to styrene is a hazard to human development or reproduction. The expert panel will also identify data gaps and research needs. CERHR expert panel meetings are open to the public with time scheduled for oral public comment. Attendance is limited only by the available meeting room space. Following the expert panel meeting and completion of the expert panel report, the CERHR will post the report on its Web site and solicit public comment on it through a **Federal Register** notice.

DATES: The expert panel meeting for styrene will be held on June 1–3, 2005. Sections 1–4 of the draft expert panel report will be available for public comment on March 18, 2005. Written public comments on the draft report must be received by May 2, 2005. Time is set-aside at the expert panel meeting on June 1, 2005 for oral public comments. Individuals wishing to make oral public comments are asked to contact Dr. Michael D. Shelby, CERHR Director, by May 25, 2005, and if possible, also send a copy of the statement or talking points at that time. Persons needing special assistance in order to attend are asked to contact Dr. Shelby at least 7 business days prior to the meeting.

ADDRESSES: The expert panel meeting for styrene will be held at the Holiday