DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood Safety and Availability (ACBSA) will hold a meeting. The meeting will be open to the public on both Tuesday December 16 and Wednesday December 17, 2008.

DATES: The meeting will take place Tuesday December 16 and Wednesday December 17, 2008 from 9 a.m. to 5 p.m.

ADDRESSES: The Hilton Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852, Phone: (301) 468–1100.

FOR FURTHER INFORMATION CONTACT: Jerry A. Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852, (240) 453–8803, FAX (240) 453–8456, e-mail *ACBSA@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Blood and plasma donations are critical to provide blood products necessary for maintaining health delivery. Over the years the safety of the blood and plasma supply has increased through vigilant review of processes and adherence to layers of safeguards. While safety and availability is paramount to the intended recipient of blood and plasma products, the pre and post donation care of the donor is also important. Commitment to donor health as well as to transfusion recipient is necessary to build a robust and healthy donor based nationally.

The Nation's potential donor population is approximately 37% of those medically eligible to donate. Approximately 16 million units of blood were collected in 2006 which exceeded demand by 7.8%. First time whole blood donors represented approximately 28.5% of the donors, while the remaining 71.5% of the donors had given previously an equivalent of 1.7 whole blood donations in the year. As the American population ages, dependence on the younger generation is more critical. In some states, donors may be 16-years-old to be eligible.

Donor selection processes have the potential to detect health abnormalities or risks which could affect the donor and even public health. Adverse events to the donor either as a result of the process of donating blood (e.g. injury, syncope, or loss of iron) or discovery of abnormal screening results can impact the donor's health. For example, iron loss can be from 220 to 290 mg in whole blood donations and from 20 to 25 mg in plasmapheresis.

Informed consent is required by FDA regulation or recommended in guidance for apheresis procedures (source plasma and platelet collections) prior to donations to include the donation procedure, the risk of the procedure, and laboratory screenings performed to reduce the risk of transmission of infectious diseases to the recipient. A written statement of understanding for whole blood donations is proposed in the Food and Drug Administration's *Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, November 2007.*

During the December 2008 meeting of the ACBSA, the Committee will be asked to comment on the responsibility of blood and plasma centers to donor and public health. Public comment will be solicited on both December 16 and 17, 2008. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Anyone planning to comment is encouraged to contact the Executive Secretary at his/her earliest convenience. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business December 12, 2008. Likewise, those who wish to utilize electronic data projection to the Committee must submit their materials to the Executive Secretary prior to close of business December 12, 2008.

Dated: November 18, 2008.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. E8–27852 Filed 11–21–08; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Test Method Evaluation Report: Validation Status of Five *In Vitro* Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products and Final Background Review Document: Validation Status of Five *In Vitro* Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products; Notice of Transmittal of ICCVAM Test Method Recommendations to Federal Agencies

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)

ACTION: Availability of the ICCVAM Test Method Evaluation Report and Final Background Review Document.

SUMMARY: NICEATM announces availability of the *ICCVAM Test Method Evaluation Report: Validation Status of Five In Vitro Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products* (NIH Publication 08–6392). The test method evaluation report (TMER) describes five *in vitro* pyrogen test methods that can be used for detecting Gram-negative endotoxin in human parenteral pharmaceuticals. The report includes ICCVAM's (a) Recommendations on uses and limitations for each test method, (b) recommendations for standardized protocols, (c) recommendations for future studies, and (d) recommendations for the development of performance standards.

ICCVAM concludes that none of these test methods can be considered as a complete replacement for the rabbit pyrogen test (RPT) for all testing situations for the detection of Gram-negative endotoxin. However, ICCVAM recommends that they can be considered for use on a case-by-case basis to detect Gram-negative endotoxin in human parenteral drugs, subject to product-specific validation to demonstrate equivalence to the RPT, in accordance with applicable U.S. Food and Drug Administration regulations. When used in this manner, these methods can reduce the number of animals needed for pyrogenicity testing. The report also recommends that these

and other *in vitro* alternative test methods be considered prior to *in vivo* pyrogenicity testing, where determined appropriate for a specific testing situation.

NICEATM also announces availability of the final *ICCVAM Background Review Document: Validation Status of Five In Vitro Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products* (NIH Publication 08–6391). The final background review document (BRD) provides the data and analyses used to assess the current validation status of these five *in vitro* test methods.

The ICCVAM TMER and supporting BRDs have been forwarded to U.S. Federal agencies for regulatory and other acceptance consideration, where applicable. Responses received will be posted on the NICEATM–ICCVAM Web site.

ADDRESSES: Electronic copies of the ICCVAM TMER and final BRD are available from the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov* or by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov* Courier address: NICEATM, NIEHS, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

In 2005, the European Centre for the Validation of Alternative Methods (ECVAM), a unit of the Institute for Health and Consumer Protection at the European Commission's Joint Research Centre, submitted BRDs for five *in vitro* pyrogen test methods proposed as replacements for the RPT to ICCVAM for formal evaluation of their scientific validity for regulatory testing purposes. ICCVAM unanimously agreed that the five submitted *in vitro* pyrogen test methods should have high priority for evaluation. On December 16, 2005, NICEATM published a **Federal Register** notice (Vol. 70, No. 241, pages 74833–74834), requesting public comments on the appropriateness and relative priority of convening an independent peer review panel (Panel) to evaluate the validation status of the five *in vitro* pyrogen test methods, the nomination of scientists to serve on the Panel, and the submission of data from *in vivo* and *in vitro* pyrogenicity testing. Based on the ECVAM BRDs as well as data and information submitted in response to the aforementioned **Federal Register** notice, NICEATM subsequently compiled a comprehensive draft BRD on the five *in vitro* pyrogen test methods and released it for public comment on December 12, 2006 (Vol. 71, No. 238, pages 74533–74534).

On February 6, 2007, NICEATM and ICCVAM convened a Panel to review the ICCVAM draft BRD for errors and omissions and to evaluate the validation status of the five *in vitro* pyrogen test methods. The Panel also reviewed the extent that the information contained in the ICCVAM draft BRD supported the ICCVAM draft test method recommendations for proposed test method uses, standardized protocols, test method performance standards, and additional studies. The Panel considered public comments made at the Panel meeting, as well as public comments submitted in advance of the meeting, before concluding their deliberations. NICEATM made the Panel's report available in May 2007 (Vol. 72, No. 89, pages 26395–26396). The ICCVAM draft BRD and draft recommendations, the Panel's report, and all public comments were made available to the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) for review and comment at their meeting on June 12, 2007 (Vol. 72, No. 83, pages 23831–23832).

ICCVAM considered the Panel's report, all public comments, and the comments of SACATM in finalizing its recommendations on the use of these five *in vitro* test methods proposed for assessing potential pyrogenicity of pharmaceuticals and other products. The ICCVAM TMER includes the ICCVAM recommendations on uses and limitations for each test method, standardized protocols, future studies, and the development of performance standards, as well as the Panel's report and **Federal Register** notices. The final BRD, which provides the supporting documentation for this report, is available as a separate document. ICCVAM forwarded the ICCVAM TMER and the supporting final BRD to U.S. Federal agencies for consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3). Agency responses to the ICCVAM test method recommendations will be made available on the NICEATM–ICCVAM Web site as they are received.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found at *http://www.iccvam.niehs.nih.gov*.

SACATM was established January 9, 2002 (Vol. 67, No. 49, page 11358), and is composed of scientists from the public and private sectors. SACATM provides advice to the Director of the NIEHS, to ICCVAM, and to NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167*.

Dated: November 7, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–27790 Filed 11–21–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

Authority: 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office for Human Research Protections (OHRP), a program