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.

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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