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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

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

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 and Tissue Safety and Availability (ACBTSA) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will take place Monday, November 9, 2015, from 8:00 a.m. – 4:30 p.m. and Tuesday, November 10, 2015, from 8:00 a.m. – 4:00 p.m.

ADDRESSES: Veterans' Health Administration National Conference Center, 2011 Crystal Drive, 1st floor Conference Center, Crystal City, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant

Secretary for Health, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852. Phone: (240) 453-8803; Fax (240) 453-8456; E-mail

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SUPPLEMENTARY INFORMATION: The ACBTSA provides advice to the Secretary through the Assistant Secretary for Health. The Committee advises on a range of policy issues to include: (1) identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.

In December 2013, the Committee made recommendations regarding the blood system. At that time, the Committee expressed concern about the ongoing reductions in blood use, the number of large scale consolidations occurring, the cost recovery issues for blood centers, and the potential effects on safety and innovation due to instability. Past recommendations made by the ACBTSA may be viewed at www.hhs.gov/bloodsafety.

This meeting will provide a focused examination of the mechanisms to fund recently approved blood safety innovations, such as pathogen reduction, bacterial testing, and infectious disease testing. It is anticipated that the implementation of these blood safety innovations will come with significant costs to blood collection centers, and it remains unclear how or if the blood

industry can afford such implementation. Speakers will include a broad range of stakeholders including blood banks, physicians, blood purchasers, and organizations that reimburse for blood and blood products.

The public will have an opportunity to present their views to the Committee during a public comment session scheduled for November 10, 2015. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is required to contact the Designated Federal Officer at his/her earliest convenience to register for time (limited to 5 minutes); registration must be completed prior to close of business on November 2, 2015. If it is not possible to provide 30 copies of the material to be distributed at the meeting, then individuals are requested to provide a minimum of one (1) copy of the document(s) to be distributed prior to the close of business on November 2, 2015. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on November 2, 2015.

Dated: October 16, 2015.

James J. Berger,

Senior Advisor for Blood and Tissue Safety Policy.