

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Development of Plasma Standards; 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 "Development of Plasma Standards." A major objective of the workshop is to assist FDA in the development of plasma standards that will address concerns encountered over the years with the preparation, storage, shipment, and use of plasma for both transfusion and the manufacture of blood products such as Factor VIII and Immune Globulin Intravenous.

Date and Time: The 2-day public workshop will be held on August 31, 2004, from 8:40 a.m. to 4:45 p.m., and on September 1, 2004, from 9 a.m. to 12:15 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), Lister Hill Center, Bldg. 38A, 8800 Rockville Pike, Bethesda, MD 20894.

The NIH campus is accessible via the Washington, DC Metro Transit System, Red Line, at the Medical Center Station. The Lister Hill Center is a short walk from the metro station, or you may take a shuttle bus that runs from the metro station to the various buildings on the campus. Because of security measures, visitors' parking is extremely limited and use of private vehicles may cause significant delays in entering the campus. Additionally,

you will be required to show a photo ID upon entry to the campus and the Lister Hill Center.

Contact Person: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: wilczek@cber.fda.gov.

Registration: Mail, fax, or e-mail the registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (see *Contact Person*) by August 17, 2004. Registration at the site will be done on a space available basis on the days of the workshop, beginning at 7:30 a.m. Because seating is limited, we recommend early registration. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is sponsoring a 2-day public workshop on plasma standards. A major objective of the workshop is to gather information on current industry practices that are in place for the manufacture of plasma, including information on the following issues and topics:

- What are appropriate freezing and storage temperatures for the components?
- What is the appropriate time to freezing?
- Should freezing and storage conditions be dependent on the final product?
- What should the recovered plasma component be called?
- What should be the expiration dating period for recovered plasma?
- Should recovered plasma be distinguished from Source Plasma? If so, how?

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Following the workshop, FDA intends to develop standards for the preparation, labeling, storage, and shipping of non-cellular blood components for transfusion and for further manufacture to ensure the safety, purity, and potency of the products.

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, rm. 12A-16, Rockville, MD 20857,

approximately 15 working days after the public workshop at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: August 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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