

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Implementation of Universal Leukoreduction; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Workshop on Implementation of Universal Leukoreduction." The purpose of the public workshop is to stimulate public discussion on how to implement pre-storage leukoreduction as a routine step in the manufacture of whole blood, red blood cells, and platelets that are intended for human transfusion.

Date and Time: The public workshop will be held on December 10, 1999, 8:30 a.m. to 4:45 p.m.

Location: The public workshop will be held at the National Institutes of Health, Natcher Conference Center, 45 Center Dr., Bldg. 45, Bethesda, MD.

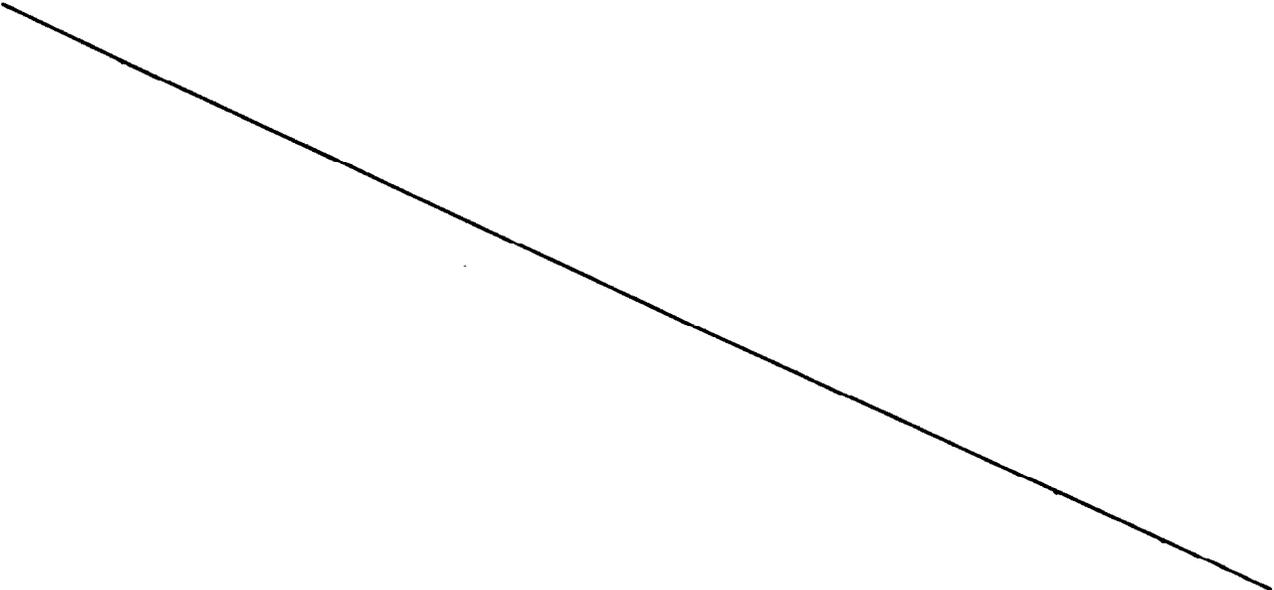
Contact: For information regarding this notice: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6129, FAX 301-827-2843. For information regarding the public workshop and registration: Jennifer Gormley, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703-351-7676, FAX 703-528-0716, E-mail: jgormley@lcgnet.com.

Registration: Early registration is recommended on or before December 3, 1999. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Jennifer Gormley (address above). Registration at the site will be on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Jennifer Gormley at least 7 days in advance.

Agenda: FDA anticipates that the ideas and experiences exchanged at the workshop will serve as a source of information for the blood industry and the public in planning for universal leukoreduction, as well as guide FDA in formulating specific regulatory recommendations. Issues to be discussed include: (1) The experiences in implementing leukoreduction as a routine blood manufacturing step and in the use of leukocyte reduced blood products; (2) whether and in what timeframe universal leukoreduction should be recognized as a blood manufacturing standard; and (3) what experiences exist to date in the United States with respect to implementing leukoreduction as a routine blood manufacturing step. An open panel discussion will include a critique of the experiences in the United States to date in implementing leukoreduction as a routine blood manufacturing step, as well as proposals for the FDA to consider in formulating new blood recommendations and regulations. All members of the transfusion community are encouraged to participate with the understanding that the workshop will focus on operational issues, rather than scientific, clinical and economic merits of universal leukoreduction.

Transcripts: Transcripts of the meeting 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 meeting at a cost of 10 cents per page. In addition, the transcript will be placed on the FDA Internet site at www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 11/23/99
November 23, 1999



William K. Hubbard
Senior Associate Commissioner for **Policy, Planning, and Legislation**

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