

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB
Display Date 7-16-02
Publication Date 7-17-02
Certifier N. Hawkins

Safety and Efficacy of Methods for Reducing Pathogens in Cellular Blood Products Used in Transfusion; 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 "Safety and Efficacy of Methods for Reducing Pathogens in Cellular Blood Products Used in Transfusion." The workshop will provide a forum for discussion of the scientific aspects of using state of the art methods for pathogen reduction in cellular blood products.

Date and Time: The 2-day public workshop will be held on August 7 and 8, 2002, from 8 a.m. to 5 p.m.

Location: The workshop will be held at Jack Masur Auditorium, National Institutes of Health, Bldg. 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact:

For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20857, 301-827-6210, FAX 301-594-1944.

For information about the public workshop: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843, e-mail at wilczek@cber.fda.gov.

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Registration: Mail, fax, or e-mail your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Joseph Wilczek by July 26, 2002. There is no registration fee for the public workshop. Space is limited, therefore, interested parties are encouraged to register early. There will be onsite registration done on a space available basis on the days of the workshop beginning at 7:30 a.m.

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 public workshop on evaluating methods for reducing pathogens in cellular blood products. Although there are no currently approved methods on the market today for pathogen reduction in cellular blood products, FDA is sponsoring this workshop for discussion of the scientific aspects of such methodologies. The objectives of the workshop are to discuss the criteria to define the efficacy of such products and appropriate ways to evaluate their toxicities to the transfusion products and to the recipients of these products. A public discussion of these topics will help the transfusion community better understand the development of these methods for cellular blood products intended for transfusion. The workshop will also help FDA prepare for the review of related applications. The public workshop agenda is posted on the FDA Internet at <http://www.fda.gov/cber/scireg.htm>.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 per page. The public workshop

transcript will also be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: 7/11/02

July 11, 2002.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn Y. Hawkins