

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Factor VIII Inhibitors; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

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The Food and Drug Administration (FDA) is announcing a public workshop entitled "Factor VIII Inhibitors." The purpose of the public workshop is to provide a forum for addressing regulatory and scientific concerns about inhibitors to Factor VIII, one of the components of blood necessary for clotting, with regard to inhibitor antibodies in Factor VIII products.

*Date and Time:* The workshop will be held on November 21, 2003, from 8 a.m. to 5 p.m.

*Location:* The workshop will be held at Lister Hill Auditorium, Bldg. 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

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

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by November 7, 2003. Early registration is recommended because seating is limited to 176 participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

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

**SUPPLEMENTARY INFORMATION:** FDA and the International Association for Biologicals (IABs) are co-sponsoring a public workshop on regulatory and scientific concerns pertaining to the potential immunogenicity of Factor VIII products. The purpose of the workshop is to provide a forum for discussion of the inhibitor phenomenon with respect to currently available products and products that are under development by various sponsors. National and international regulatory authorities, manufacturers, clinicians, and academics will discuss their experiences with this issue regarding preclinical testing requirements, the results of clinical trials, and post-marketing surveillance. Other issues to be discussed at the workshop include properties of Factor VIII inhibitor assays, epidemiological aspects of inhibitor formation, and the design of prospective clinical studies. The public workshop agenda is posted on the FDA Internet at <http://www.fda.gov/cber/meetings/fctrviii112103.htm>.

Dated: 10.10.03  
October 10, 2003.

*Jeffrey Shuren*

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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*Robert Nelson*