

DMB

Display Date	11-17-98
Publication Date	11-18-98
Certifier	

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Pilot Program for Streamlining Licensure of Blood and Blood Components; Public Workshop**

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

**ACTION:** Notice.

---

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Pilot Program for Streamlining Licensure of Blood and Blood Components." At the workshop, FDA will describe a pilot program that is under development and solicit input from blood and blood component manufacturers about streamlining the licensure review process.

*Date and Time:* The workshop will be held on Wednesday, December 9, 1998, 8:30 a.m. to 4:30 p.m.

*Location:* The workshop will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD.

*Contact:* Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, or Cody Bridges, Laurel Consulting Group, 3030 Clarendon Blvd., suite 240, Arlington, VA 22201, 703-351-7676, FAX 703-528-0716, or email "cbridges@lcnnet.com".

*Registration:* Send or fax registration information (including name, title, firm name, address, telephone, and fax number) to Cody Bridges by Friday, November 27, 1998. Registration at the site will be done 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.

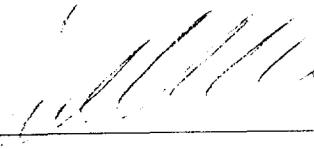
If you need special accommodations due to a disability, please contact Cody Bridges at least 7 days in advance.

*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 days after the workshop at a cost of 10 cents per page. The workshop transcript will also be available on CBER's website at "<http://www.fda.gov/cber/minutes/workshop-min.htm>".

*Supplementary Information:* FDA will sponsor a 1-day workshop to provide guidance to blood and blood component manufacturers on how to certify that they are in compliance with pilot monographs in lieu of traditional blood applications and supplements. Two pilot monographs to be discussed at the workshop apply to irradiation of blood and blood components and red blood cell immunization programs.

The objectives of the workshop are to describe FDA's pilot program and to solicit input from blood and blood component manufacturers about streamlining the licensure review process for certain blood products.

Dated: November 10, 1998  
November 10, 1998



---

William K. Hubbard  
Associate Commissioner for Policy Coordination

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**  
*Jen Windsor*