type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web on the CDRH home page at ''http://www.fda.gov/cdrh'' or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

FDA has received the following petition requesting an exemption from premarket notification for a class II device:

1. Hearing Industries Association, 21 CFR 874.1050, *Audiometer.*

IV. Comments

Interested persons may, on or before December 18, 1998, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 5, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–30813 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

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@lcgnet.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.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30751 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 10, 1998, 8 a.m. to 5:30 p.m. and December 11, 1998, 8 a.m. to 3 p.m.

Location: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138