Web (WWW). Both the computerized report and forms available via the WWW must be submitted via paper.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2301	510.302a	190	19.74	3,750	0.5	1,875
Form FDA 1932	510.302b	190	15.25	2,900	1.0	2,900
Form FDA 1932a (voluntary)	510.302b	100	1.0	100	1.0	100
Total Burden Hours						4,875

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Response per Recordkeeper	Hours per Recordkeeper	Total Hours
510.300(a) and 510.301(a)	190	15.26	3,750	10.35	38,812
510.300(b) and 510.301(b)	190	19.74	2,900	0.50	1,450
Total Burden Hours					40,262

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: November 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30752 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0833]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice of a petition requesting exemption from the premarket notification requirements for a class II device, the audiometer. FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by December 18, 1998.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94–295)), as amended by the Safe Medical Devices Act of 1990 (Pub. L. 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendment devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976, (generally referred to as postamendment devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m)(1) of the act which requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each

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