number. OMB has now approved the information collection and has assigned OMB control number 0910–0037. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–26221 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0926]

Agency Information Collection Activities; Announcement of OMB Approval; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Under the Federal Import Milk Act'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 1999 (64 FR 44019), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0212. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–26223 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Training on Electronic Records; Electronic Signatures; Satellite Conference; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of satellite conference and public meeting.

The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Center for Biologics Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and the Center for Veterinary Medicine) is announcing the following satellite conference and public meeting entitled ''Industry Training on 21 CFR Part 11.'' The topics to be discussed are current good manufacturing practices, electronic recordkeeping requirements, validation of electronic recordkeeping systems, and the answers to frequently asked questions.

Date and Time: The satellite conference and public meeting will be held on Thursday, October 21, 1999, 1 p.m. to 4 p.m., eastern standard time.

Contact: Laura C. Woolf, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–3840, FAX 301–827–3843, e-mail: woolf@cber.fda.gov.

SUPPLEMENTARY INFORMATION: The satellite conference announced in this document is a repeat of the satellite conference at the public meeting announced in the **Federal Register** of December 14, 1998 (63 FR 68778). The satellite conference is intended to inform FDA-regulated industries, and especially, small business about the requirements for electronic recordkeeping according to 21 CFR part 11 and to provide for a dialogue with FDA. The satellite conference addresses the requirements of both the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that mandates outreach activities by Government agencies directed to small businesses and section 406(b) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) that calls for involvement of FDA with its stakeholders in cooperative activities to ensure the quality of marketed products.

There are no meeting sites and registration is not necessary for the satellite conference and public meeting. To view the satellite conference, companies with satellite capability will need to downlink the coordinates. The coordinates are as follows: C Band Galaxy 6 @ 99 west Transponder 20.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–26222 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices 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 October 28, 1999, 8:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a premarket notification for an over-the-

counter device that measures triglycerides from whole blood fingersticks.

Procedure: On October 28, 1999, from 9 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 15, 1999. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. and between approximately 1:45 p.m. and 2:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 15, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 28, 1999, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information regarding pending and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 30, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–26219 Filed 10–7–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4130]

Medical Devices; Draft Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems.'' This draft guidance document provides guidance to industry on certain information about assembly, installation, adjustment, and testing that original equipment manufacturers must disclose at cost to users and assemblers of diagnostic x-ray equipment systems. The scope of the disclosure requirement needs clarification due to the development of computerized technology and inclusion in software of specific information that some manufacturers consider proprietary. This draft guidance explains what information must be disclosed to ensure that diagnostic x-ray components or diagnostic x-ray systems are able to meet applicable Federal performance standards that reduce or maintain x-ray exposure to the patient and operator at the lowest possible level.

DATES: Written comments concerning this draft guidance must be submitted by January 6, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance must be submitted to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas M. Jakub, Center for Devices and Radiological Health (HFZ–322), Food and Drug Administration, 9024 Gaither Rd., Rockville, MD 20850, 301–594–4591.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the Radiation Control for Health and Safety Act of 1968 (RCHSA) Public Law 90–602, is to protect the public from the unnecessary or dangerous electronic product radiation by establishing performance standards. Under the authority of RCHSA, now incorporated into the Federal Food, Drug, and Cosmetic Act (the act) at section 532 (21 U.S.C. 360ii), FDA issued regulations that require manufacturers to provide information to assemblers, users, and any one else upon request, that is needed to ensure compliance with applicable federal performance standards. The performance standards establish calculated criteria that reduce or maintain x-ray exposure to the patient and operator at the lowest possible level. The scope of information that manufacturers must provide includes instructions, installation, adjustment, and testing (AIAT) of x-ray components (21 CFR 1020.30(g)). With the advancement of technology, use of computers and corresponding software, manufacturers need clarification about what information must be disclosed to satisfy the requirements of AIAT disclosure. The regulation states that manufacturers shall provide AIAT information, ''* * * at cost not to exceed the cost of publication and distribution* * *.'' The cost manufacturers charge for AIAT software required under the guidance document should permit the manufacturer to recover its expenses in producing the additional unit of the software, but should not include initial development costs or a profit margin. FDA is especially interested in receiving comments from interested parties on the issue of cost under the performance standard.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on information disclosure by manufacturers to assemblers for diagnostic x-ray systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second