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]

BILLING CODE 4160–01–F

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Medical Devices; Draft Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems.'' This draft guidance document provides guidance to industry on certain information about assembly, installation, adjustment, and testing that original equipment manufacturers must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 This draft guidance explains what information must be disclosed to ensure that diagnostic x-ray components or diagnostic x-ray systems are able to meet applicable Federal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

voice prompt press 2, and then enter the document number (2619) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems'' will be available at http://www.fda.gov/cdrh/oc.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–26220 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–3028]

Medical Devices: Draft Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease; 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 Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease.'' This draft guidance is intended to provide current insights on the design, data collection, and data analysis of studies that are important to the premarket approval application (PMA) approval process for in vitro diagnostic (IVD) devices pertaining to HCV. This draft guidance document represents the agency's current thinking regarding PMA's for IVD devices that pertain to HCV infection. This draft guidance is neither final nor is it in effect at this time.

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 draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease'' 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 on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide recommendations for studies to demonstrate performance of assays for detecting evidence of infection with HCV. A meeting of the Microbiology Devices Advisory Panel was held on February 12, 1998, to obtain suggestions and recommendations from the panel regarding scientific information necessary for premarket approval of tests for hepatitis viruses. Following the panel meeting and subsequent discussions between FDA and representatives of the Health Industry Manufacturers Association (HIMA), HIMA developed a draft guidance document for tests to detect HCV and submitted it to FDA. This draft guidance document issued by FDA reflects modifications to HIMA's proposed document and, therefore, does not necessarily reflect HIMA's original or current position.

II. Significance of Guidance

This draft guidance represents the agency's current thinking regarding the content of PMA's for IVD devices pertaining to HCV. 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 draft guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease'' 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 the second voice prompt press 2, and then enter the document number (1353) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.