Dated: March 21, 2001.

Sue Swenson,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 01–7963 Filed 3–30–01; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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). The meeting will be open to the public.

Name of Committee: Circulatory System 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 April 23, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 171, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a peripheral stent used in the treatment of stenotic or occluded femoral or popliteal arteries. Subsequently, the committee will discuss clinical study design issues for peripheral stents used in the treatment of stenotic or occluded iliac arteries. Background information and questions for the committee will be available to the public on April 20, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

Procedure: 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 April 18, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 18, 2001, 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.

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

Dated: March 26, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–7995 Filed 3–30–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0129]

Medical Devices Draft Guidance for the Implementation of the Biomaterials Access Assurance Act of 1998; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Implementation of the Biomaterials Access Assurance Act of 1998.'' The Biomaterials Access Assurance Act of 1998 (BAA98) allows persons to petition FDA for a declaration stating that a biomaterials supplier should have registered as a medical device establishment or listed its products with FDA but has not done so. This draft guidance provides information that FDA believes should be included in the petition, the procedures FDA believes should be followed in submitting the petition, and the procedures that the Center for Devices and Radiological Health (CDRH) intends to adopt for addressing petitions for declaration. This guidance is neither final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by July 2, 2001. Submit written comments on the information collection requirements by June 1, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Implementation of the Biomaterials Access Assurance Act of 1998'' 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Harold A. Pellerite, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4692, ext. 159.

SUPPLEMENTARY INFORMATION:

I. Background

BAA98 (21 U.S.C. 1601–1606) establishes a mechanism to protect some biomaterials suppliers of implanted medical devices from liability in civil suits for harm caused by an implant. However, biomaterials suppliers are not protected from liability when they fail to meet specifications, act as a manufacturer or seller of the implanted devices, or have substantial economic ties to either the manufacturer or seller. For the purposes of BAA98, a ''biomaterials supplier'' is defined as an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implanted medical device. BAA98 also provides that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of an FDA declaration that states that the supplier was required to register, under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), but failed to do so, or was required to list its device, under section 520(j) of the act (21 U.S.C. 360(j)), but failed to do so. BAA98 allows persons to petition FDA for a declaration stating that a biomaterials supplier should have registered or listed with FDA but has not done so.

The draft guidance discusses the prerequisites for filing a petition for declaration and suggests information to be included in the petition. The following three prerequisites must be

met in order to file a petition: (1) A civil suit has been filed in State or Federal court alleging that an implant directly or indirectly caused harm; (2) the suit was filed after August 13, 1998; and (3) the manufacturer of the implant was named as a party to the civil action. Petitioners are also requested to identify the final product and its intended use; the activities the supplier performs with respect to the device; and the name as well as the type of entity or person to which the supplier sends the device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on BAA98. 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 statutes and regulations.

The agency has adopted good guidance practices (GGP's), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive a copy of the draft guidance entitled ''Implementation of the Biomaterials Access Assurance Act of 1998'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1324) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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/comp/guidance/1324.pdf.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Implementation of the Biomaterials Access Assurance Act of 1998

BAA98 establishes a mechanism to protect biomaterial suppliers of implanted medical devices from liability in civil actions. BAA98 includes exceptions for when protection from liability is not available to suppliers. One of those exceptions is when a supplier acts as a manufacturer of the implanted device. BAA98 says that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of an FDA declaration that the supplier was required to register under section 510 of the act and failed to do so, or was required to list its device under section 520(j) of the act and failed to do so.

BAA98 allows persons to petition FDA for a declaration that a biomaterials supplier should have registered its establishment or listed its device with FDA, and failed to do so. Petitioners are requested to include information about the prerequisites for filing a petition. This information includes the following: (1) A civil suit has been filed in State or Federal court alleging that an implant directly or indirectly caused harm; (2) the suit was filed after August 13, 1998; and (3) the manufacturer of the implant was named as a party to the civil action. Petitioners are also requested to include information to identify the following: (1) The final product and how it is intended to be used, (2) the activities the supplier performs on the device, and (3) the name as well as type of entity or person to which the supplier sends the device. These draft reporting requirements are intended to provide FDA with sufficient information to show that the prerequisites for filing the petition are met and determine whether a biomaterial supplier should have registered its establishment or listed its device with FDA, and failed to do so.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
5	1	5	1	5

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

BAA98 became effective August 13, 1998. Up until the current date, no petitions for declaration have been filed with FDA. However, FDA believes that in future years a handful (estimated at 5) of petitioners may file with the agency. FDA estimates that respondents would take approximately 1 hour to gather the requisite information and draft a petition. The likely respondents to this collection of information are persons involved in civil actions based

on harm arising from an implanted medical device.

V. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by July 2, 2001. Submit two copies of any comments, 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. Written comments concerning the information collection requirements must be received by Dockets Management Branch by June 1, 2001. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 26, 2001.

Linda S. Kahan,

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

[FR Doc. 01–7956 Filed 3–30–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4130]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA.'' This guidance document is intended to provide guidance to the industry about meeting requirements for disclosure to assemblers, and to others upon request, of certain types of information at a cost not to exceed the cost of publication and distribution to ensure that x-ray systems will meet Federal performance standards.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas M. Jakub, Center for Devices and Radiological Health (HFZ–322), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4591.

SUPPLEMENTARY INFORMATION:

I. Background

This final Level 1 guidance document entitled ''Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' is intended to provide guidance to diagnostic x-ray system manufacturers, users, assemblers, and others concerning the requirement to disclose information about the assembly, installation, adjustment, and testing (AIAT) of x-ray components for diagnostic x-ray systems. (See § 1020.30(g) (21 CFR 1020.30(g))). With the advancement of technology and the use of computers with corresponding software, manufacturers need clarification about what information must be disclosed to satisfy the requirements of AIAT disclosure. This final Level 1 guidance document supersedes the corresponding draft guidance entitled ''Draft Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems,'' which was announced in the **Federal Register** on October 8, 1999 (64 FR 54901). The comment period closed on January 6, 2000. The agency received several comments and recommendations concerning the draft guidance. A number of comments received by the agency addressed issues that do not fall within the scope of the guidance and § 1020.30(g). The final guidance contains only minor changes from the draft guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on information disclosure by manufacturers to assemblers for diagnostic x-ray systems, as required by § 1020.30(g). 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 requirement of the applicable statutes and regulations.

III. Electronic Access

In order to receive ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand 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 (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 Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA,'' 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; Final Guidance for Industry and FDA'' is also available at http://www.fda.gov/cdrh/comp/2619.html. Guidance documents are also available on the Dockets Management Branch website at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management