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