at any time. States that are interested in a project to be considered for approval in fiscal year 1998 may qualify for priority attention by sending a Letter of Intent before March 16, 1998 and submitting a full proposal by April 30, 1998.

ADDRESSES: All Letters of Intent and complete proposals should be submitted to Michael W. Ambrose, Children's Bureau, Administration on Children, Youth and Families, 330 C Street, SW, Room 2068, Washington, DC 20201. Facsimile transmission of Letters of Intent ONLY will be accepted providing it is followed by an original copy. The FAX number is (202) 260–9345.

SUPPLEMENTARY INFORMATION: This announcement and Information Memorandum Number ACYF–CB–IM–98–01 do not create any right or benefit, substantive or procedural, enforceable at law or equity, by any person, or entity, against the United States, its agencies or instrumentalities, the States, or any other person.

Dated: February 18, 1998.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 98–5522 Filed 3–3–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee on Mental Retardation; Meeting

Agency Holding the Meeting: President's Committee on Mental Retardation.

Time and Date: March 13–15, 1998; March 13–12 p.m.–5 p.m.; March 14–9 a.m.–5 p.m.; March 15–9 a.m.–12 p.m.

Place: Renassiance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC.

Status: Full Committee Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All meeting sites are barrier free.

To be Considered: The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness, relating to individuals with mental retardation.

The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs and supports for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

Contact Person for More Information: Gary H. Blumenthal, 352–G Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201–0001, (202) 619–0634.

Dated: February 25, 1998.

Gary H. Blumenthal,

Executive Director, President's Committee on Mental Retardation.

[FR Doc. 98–5524 Filed 3–3–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0517]

Medical Devices; Device Tracking; New Orders to Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the agency has issued new orders to manufacturers of devices that were subject to tracking. These new orders became effective on February 19, 1998, and require manufacturers to continue tracking the devices under the revised tracking provisions of the recently enacted Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA allows the agency discretion in issuing orders to manufacturers to track devices that meet certain criteria. FDA is soliciting comments on what factors should be considered in exercising its discretion in determining whether the agency should not track a particular device, even though it meets the statutory criteria. FDA specifically is requesting comments on whether there are factors that FDA should consider in exercising its discretion in releasing certain devices listed in this notice from tracking requirements. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance that addresses device tracking under FDAMA, including the application of certain requirements under the current tracking regulations.

DATES: Written comments concerning this notice may be received by May 4, 1998.

ADDRESSES: Written comments may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Device Act of 1990 (the SMDA) added tracking provisions to the Federal Food, Drug, and Cosmetic Act (the act) by adding new section 519(e) of the act (21 U.S.C. 360i(e)). As added by the SMDA, section 519(e)(1) of the act required the adoption of a method of tracking, even if FDA did not issue an order. Specifically, any person registered under section 510 of the act (21 U.S.C. 360), and engaged in the manufacture of a device, had to track the device if the failure of that device would be reasonably likely to have serious adverse health consequences, and the device was either a permanently implantable device or a life sustaining or life supporting device used outside a device user facility. Section 519(e)(2) of the act also authorized FDA to ''designate'' other devices that must be tracked.

FDA issued regulations implementing tracking requirements in the **Federal Register** of August 16, 1993 (58 FR 43442). The regulations became effective on August 29, 1993, and are codified in part 821 (21 CFR part 821). Under tracking provisions established by the SMDA, manufacturers had the responsibility to identify devices that met the statutory criteria for tracking. For illustrative purposes, the agency set out in § 821.20(b)(1) and (b)(2) a list of example devices it considered subject to mandatory tracking under section 519(e)(1) of the act. Devices designated for tracking by FDA under section 519(e)(2) of the act were listed in § 821.20(c).

FDAMA was enacted on November 21, 1997. Section 211 of FDAMA amended section 519(e)(1) of the act to authorize FDA, in its discretion, to issue orders that require a manufacturer to track a class II or class III device if the failure of the device would be reasonably likely to have serious adverse health consequences, or the device is intended to be implanted in the human body for more than 1 year, or is life sustaining or life supporting and used outside a device user facility. Section 519(e)(2) of the act, as amended by FDAMA, provides that patients receiving a tracked device may refuse to provide their name, address, social security number, or other identifying information, for tracking purposes. Accordingly, tracking may be required

under section 519(e), as amended by FDAMA, only if FDA issues an order and only if the criteria described previously are met. FDAMA tracking provisions became effective on February 19, 1998.

II. Implementation of FDAMA Tracking Authority

FDA has initiated the measures identified in section II of this document to implement the tracking authority given to the agency under section 519(e) of the act, as amended by FDAMA.

A. Manufacturer Notification/Public Meeting

On December 19, 1997, FDA sent letters to manufacturers identified as having responsibilities to track devices under section 519(e) of the act. These letters advised the firms that FDAMA would implement important statutory changes in these areas and that FDA had announced in the **Federal Register** of December 18, 1997 (62 FR 66373), that it would conduct a public meeting on January 15, 1998, to discuss such changes. The letter also advised that existing device tracking requirements imposed by previously issued FDA regulations or FDA orders would remain in effect, until FDA notified a firm of any changes in its responsibilities.

At the January 15, 1998, public meeting held in Rockville, MD, written and oral comments were received from consumer groups, clinicians, manufacturers and device industry associations. These comments ranged from considering clinical management issues, and the use of alternative tracking mechanisms, to considering the likelihood of device failure.

B. Issuance of Tracking Orders

On February 11, 1998, FDA issued orders to manufacturers who would be required to track their devices under section 519(e), as revised by FDAMA. These orders became effective on February 19, 1998. The devices subject to these new orders are the types of devices currently identified in the agency's tracking regulations at 21 CFR 821.20(b)(1), (b)(2), and (c), except that arterial stents and intraocular lenses have been added. FDA has determined that these devices meet the criteria under revised section 519(e) of the act. These devices are as follows:

TABLE 1.—DEVICES MEETING THE CRITERIA UNDER REVISED SECTION 519(e) OF THE ACT

21 CFR Section	Classification
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3460	Vascular graft prosthesis of 6 millimeters and greater diameter
(no cite)	Total temporomandibular joint prosthesis
(no cite)	Glenoid fossa prosthesis
(no cite)	Mandibular condyle prosthesis
(no cite)	Interarticular disc prosthesis (interpositional implant)
870.3545	Ventricular bypass (assist) device
870.3610	Implantable pacemaker pulse generator
870.3680(b)	Cardiovascular permanent pacemaker electrode
870.3800	Annuloplasty ring
870.3925	Replacement heart valve
(no cite)	Automatic implantable cardioverter/defibrillator
878.3720	Tracheal prosthesis
882.5820	Implanted cerebellar stimulator
882.5830	Implanted diaphragmatic/phrenic nerve stimulator
(no cite)	Implantable infusion pumps
(no cite)	Arterial stents (used in coronary arteries or peripheral arteries)
886.3600	Intraocular lens
868.2375	Breathing frequency monitors (apnea monitors) (including ventilatory efforts monitors)
868.5895	Continuous ventilator
870.5300	DC-defribrillator and paddles
876.3350	Penile inflatable implant
878.3530	Silicone inflatable breast prosthesis
878.3540	Silicone gel-filled breast prosthesis
876.3750	Testicular prosthesis, silicone gel-filled
(no cite)	Silicone gel-filled chin prosthesis
(no cite)	Silicone gel-filled angel chik reflux valve
880.5725	Infusion pump

C. FDA Review/Reconsideration of Devices Requiring Tracking

Although FDA has issued orders to subject all of the devices described previously to tracking requirements under section 519(e) of the act, as revised by FDAMA, FDA recognizes that the new law provides the agency with discretion to not require tracking of devices that meet the statutory criteria. FDA believes that certain factors may indicate that tracking for some devices, even though they meet the statutory criteria under section 519(e) of the act, may not be necessary to protect the public health. Accordingly, FDA is soliciting comments on what factors FDA should consider in exercising its discretion to require, or not to require, tracking of those devices that meet the statutory criteria stated in section 519(e) of the act. Comments should not merely identify what devices that meet the statutory tracking criteria should or should not be tracked, but should fully address the factors that should be relevant in the agency's exercise of discretion. After reviewing the comments received in response to this document, FDA will determine what factors should be considered in exercising its discretion. After determining what those factors should be, FDA will rescind any orders issued under section 519(e) of the act, if the agency determines that tracking is not necessary to protect the public health.

The agency has requested comments on the implementation of tracking requirements enacted by FDAMA. After considering the: (1) Agency's experience; (2) information provided by the public at the January 15, 1998, meeting; and (3) written submissions received afterwards, the agency has

tentatively identified several products that are subject to the February 1998, tracking orders for which there may be factors that may be considered in the agency's exercise of discretion not to track a particular device, even though it meets the statutory criteria. These devices are the following:

TABLE 2.—PREVIOUSLY ''MANDATED'' DEVICES—PERMANENTLY IMPLANTED DEVICES

21 CFR Section	Classification
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3460	Vascular graft prosthesis of 6 millimeters and greater diameter
(no cite)	Interarticular disc prosthesis (interpositional implant)
870.3800	Annuloplasty ring
878.3720	Tracheal Prosthesis
(no cite)	Arterial stents (used in coronary arteries or peripheral arteries)

TABLE 3.—PREVIOUSLY ''DESIGNATED'' DEVICES

21 CFR Section	Classification
876.3350	Penile inflatable implant
878.3530	Silicone inflatable breast prosthesis
878.3540	Silicone gel-filled breast prosthesis
876.3750	Testicular prosthesis, silicone gel-filled
(no cite)	Silicone gel-filled chin prosthesis
(no cite)	Silicone gel-filled angel chik reflux device
880.575	Infusion pump (i.e., those designated and labeled for use exclusively for fluids with low potential risks, e.g., enteral feeding, anti-infectives)

The agency invites comments on these devices, as well as any other devices that should be added or deleted from the list of those devices subject to tracking requirements.

III. Comments

Interested persons may, by or before May 4, 1998 submit to the Dockets Management Branch (address above) written comments concerning 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 notice and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 25, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–5520 Filed 2–27–98; 3:14 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0132]

FDA Modernization Act of 1997: Guidance on Medical Device Tracking; Availability

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance on Medical Device Tracking.'' This guidance is intended to provide guidelines to manufacturers and distributors about their responsibilities for medical device tracking under the Food, Drug and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act (FDAMA). This guidance addresses what statutory and regulatory tracking requirements have changed and what requirements remain the same under the FDAMA amendments. The agency requests comments on this guidance. Elsewhere, in this issue of the **Federal Register**, FDA is announcing new orders to manufacturers of devices that were subject to tracking.

DATES: Written comments concerning this guidance must be received by May 4, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the ''Guidance on Medical Device Tracking'' (available on 3.5'' diskette) to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), 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.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

Section 211 of the Food and Drug Administration Modernization Act (Pub. L. 105–115) (FDAMA) amended the tracking provisions of section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(e)), authorizing FDA to order manufacturers to track devices meeting criteria established under FDAMA. These amendments became effective on February 19, 1998. This guidance explains device tracking under section 519(e) of the act, as amended by FDAMA, including: (1) Changes in the criteria requiring devices to be tracked; (2) the rights of patients to refuse to disclose identifying information; (3) the discretion FDA has in issuing tracking orders; (4) FDA review and reconsideration of devices meeting tracking criteria; and (5) the application of certain requirements in the agency's existing tracking regulations in 21 CFR part 821.

This guidance represents the agency's current thinking on medical device