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