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

tracking under tracking provisions revised by FDAMA. 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. This is a Level 1 guidance. Public comment prior to implementation of this guidance document is not required because the guidance is needed to implement new statutory tracking requirements enacted by FDAMA. The agency is providing for a comment period of 60 days after the date of publication of the **Federal Register** notice of availability for the document.

II. Electronic Access

In order to receive the guidance entitled ''Guidance on Medical Device Tracking'' 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 (169) 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 by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the WWW. Updated on a regular basis, the CDRH Home Page includes ''Guidance on Medical Device Tracking,'' 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 Medical Device Tracking'' will be available at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, by or before May 4, 1998 submit to the Dockets Management Branch (address above) written comments regarding this guidance. 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 guidance document 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. 98–5519 Filed 2–27–98; 3:14 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1036–N]

Medicare Program; March 16–17, 1998, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for March 16, 1998, from 9:00 a.m. until 5 p.m., March 17, 1998, from 8:30 a.m. until 12:00 noon e.s.t.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jeffrey Kang, M.D., Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201, (202) 690–7874.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Gary C. Dennis, M.D.; Mary T. Herald, M.D.; Ardis Hoven, M.D.; Sandral Hullett, M.D. (Renominated-Pending Selection); Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Marc Lowe, M.D.; Derrick K. Latos, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; and Kenneth M. Viste, Jr., M.D. (Renominated-Pending Selection). The chairperson is Kenneth M. Viste, Jr., M.D.

Council members will receive an update on Medicare+Choice Program and Children's Health Initiative. The agenda will provide for discussion and comment on the following topics:

- Documentation Guidelines.
- Practice Expense.
- Physician Supervision of Allied Health Professions.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12 noon, March 6, 1998, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12 noon, March 12, 1998. Anyone who is