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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, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised final guidance entitled "Guidance on Medical Device Tracking." It replaces the previous final guidance issued on March 4, 1998. This revised final guidance provides guidelines to manufacturers and distributors concerning their responsibilities for medical device tracking under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the revised final guidance entitled "Guidance on Medical Device Tracking" 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 "Guidance on Medical Device Tracking" to the contact person (address below). See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4618.

SUPPLEMENTARY INFORMATION:

I. Background

Section 211 of FDAMA (Pub. L. 105–115) amended the tracking provisions of section 519(e) of the act (21 U.S.C. 360i(e)) to authorize FDA, at 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. The FDAMA tracking provisions became effective on February 19, 1998.

On January 15, 1998, FDA conducted a public meeting to discuss FDAMA changes in section 519(e) of the act. Comments were received concerning factors FDA should consider in determining what devices are subject to FDAMA tracking requirements. On February 11, 1998, FDA issued tracking orders, under the revised FDAMA tracking provisions which became effective on February 19, 1998, to manufacturers of devices that were subject to tracking previously under the Safe Medical Devices Act of 1990 (the SMDA) provisions (21 CFR 821.20(b)(1), (b)(2), and (c)). Additionally, tracking orders were issued to manufacturers of intraocular lenses and arterial stents that had not been subject to tracking under the SMDA provisions (63 FR 10638, March 4, 1998). Tracking orders were also issued on December 14, 1998, to tissue banks that manufacture and distribute dura mater.

On March 4, 1998, FDA announced the availability of the “Guidance on Medical Device Tracking” (63 FR 10638 at 10640). This final draft guidance was issued as a Level 1 guidance under the agency’s Good Guidance Practices (GGP’s) (62 FR 8961, February 27, 1997). The guidance explained: (1) Revised tracking criteria in section 519(e) of the act, as amended by FDAMA; (2) patients’ rights to refuse information disclosure; (3) FDA’s discretion in issuing tracking orders; (4) FDA’s review and reconsideration of devices subject to FDAMA tracking criteria; and (5) the regulatory application of tracking requirements in 21 CFR part 821.

Through the January 1998 meeting and the March 1998 **Federal Register** notices, FDA solicited public comment on what factors in addition to the revised statutory criteria the agency

should consider in exercising its discretion to require, or not to require, the tracking of devices. As a consequence of these comments, FDA believes it should consider the following factors, as ascertained from available premarket and postmarket information, in determining whether to issue a tracking order for a particular type of device: (1) Likelihood of sudden, catastrophic failure; (2) likelihood of significant adverse clinical outcome; and (3) need for prompt professional intervention.

This revised final guidance replaces the March 1998 guidance and reflects the factors FDA may consider in determining which devices should be tracked. The list of tracked devices identified in the March 1998 guidance also has been revised in this final guidance, based on the additional factors noted previously and identifies 14 categories of devices that have been released from FDAMA tracking requirements under the tracking requirement rescission orders issued by FDA in August 1998. It also identifies the 16 categories of devices currently subject to tracking orders. The agency added one category, dura mater, which was the subject of tracking orders issued by the agency which became effective on December 14, 1998. The remaining 15 device types were the subject of tracking orders issued by the agency which became effective on February 19, 1998. Upon further review and reconsideration, FDA has determined that these particular devices meet the statutory tracking criteria under section 519(e) of the act and, upon failure, would likely exhibit the factors noted previously that FDA believes warrants their tracking. The agency may add or remove devices from the list of tracked devices as a result of its review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance, or other information.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device tracking requirements, as amended 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.

The agency has adopted GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive "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 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 revised final guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer 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/ochome.html>".

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current 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: 2/3/99

February 3, 1999

Linda S. Kahan

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Center for Devices and Radiological Health

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