(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

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SOURCE: 58 FR 43447, Aug. 16, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 821.1 Scope.

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: 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 the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, as a “tracked device.”

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer’s device tracking effort, the legal responsibility for complying with this part rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

(c) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufacturer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes such failure, misbrands the device within the meaning of section 502(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

(d) Any person subject to this part who permanently discontinues doing business is required to notify FDA at the time the person notifies any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues
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§ 821.3 Definitions.

The following definitions and terms apply to this part:


(b) Importer means the initial distributor of an imported device who is subject to a tracking order. “Importer” does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousers.

(c) Manufacturer means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in §807.3(d) of this chapter.

(d) Device failure means the failure of a device to perform or function as intended, including any deviations from the device’s performance specifications or intended use.

(e) Serious adverse health consequences means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

(f) Device intended to be implanted in the human body for more than 1 year means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include a device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.

(g) Life-supporting or life-sustaining device used outside a device user facility means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physicians’ offices are not device user facilities and, therefore, devices used therein are subject to tracking if they otherwise satisfy the statutory and regulatory criteria.

§ 821.2 Exemptions and variances.

(a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

(b) A request for an exemption or variance shall be submitted in the form of a petition under §10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

(1) The name of the device and device class and representative labeling showing the intended use(s) of the device;

(2) The reasons that compliance with the tracking requirements of this part is unnecessary;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and

(4) Other information justifying the exemption or variance.

(c) An exemption or variance is not effective until the Director, Office of Compliance, CDRH, approves the request under §10.30(e)(2)(i) of this chapter.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 72 FR 17399, Apr. 9, 2007]

§ 821.3 Definitions.

The following definitions and terms apply to this part:


(b) Importer means the initial distributor of an imported device who is subject to a tracking order. “Importer” does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousers.

(c) Manufacturer means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in §807.3(d) of this chapter.

(d) Device failure means the failure of a device to perform or function as intended, including any deviations from the device’s performance specifications or intended use.

(e) Serious adverse health consequences means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

(f) Device intended to be implanted in the human body for more than 1 year means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include a device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.

(g) Life-supporting or life-sustaining device used outside a device user facility means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physicians’ offices are not device user facilities and, therefore, devices used therein are subject to tracking if they otherwise satisfy the statutory and regulatory criteria.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 73 FR 34860, June 19, 2008]
§ 821.4 Imported devices.

For purposes of this part, the importer of a tracked device shall be considered the manufacturer and shall be required to comply with all requirements of this part applicable to manufacturers. Importers must keep all information required under this part in the United States.

Subpart B—Tracking Requirements

§ 821.20 Devices subject to tracking.

(a) A manufacturer of any class II or class III device that fits within one of the three criteria within § 821.1(a) must track that device in accordance with this part, if FDA issues a tracking order to that manufacturer.

(b) When responding to premarket notification submissions and remarket approval applications, FDA will notify the sponsor by issuing an order that states that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, the sponsor must track the device.

§ 821.25 Device tracking system and content requirements: manufacturer requirements.

(a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

(1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for tracked devices that are intended for use by a single patient over the life of the device, after distribution to or implantation in a patient:

(i) The lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the device;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under § 821.55(a);

(iv) The date the device was provided to the patient;

(m) Any term defined in section 201 of the act shall have the same definition in this part.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002]