

Food and Drug Administration, HHS

§ 806.2

during the procedure about which the report is being made: the name of the manufacturer, model number, serial number, and the warranty expiration date.

(h) For each device (pulse generator, atrial lead, ventricular lead) removed or replaced during the procedure about which the report is being made: the name of the manufacturer; model number; serial number; the warranty expiration date, if known; the date the device was initially implanted, if known; whether a device that was replaced was left in the body; if the device was not left in the body, whether it was returned to the manufacturer.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0234)

§ 805.20 How to submit information.

Information shall be submitted to the registry in the form and manner required under general instructions of the Medicare program (see 42 CFR 409.19(a) and 410.64(a)).

§ 805.25 Confidentiality.

(a) FDA and HCFA will keep confidential, and will not reveal to the public, any specific information that identifies by name a recipient of any pacemaker device or lead or that would otherwise identify a specific recipient.

(b) Public disclosure of all other information under this part will be governed by the Freedom of Information Act (5 U.S.C. 552), the Privacy Act of 1974 (5 U.S.C. 552a), the Department of Health and Human Services' public information regulations (45 CFR part 5), FDA's public information regulations (21 CFR part 20), and HCFA's public information regulations (subpart B of 42 CFR part 401).

PART 806—MEDICAL DEVICE CORRECTIONS AND REMOVALS

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AUTHORITY: Secs. 502, 510, 519, 520, 701, and 704, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

SOURCE: 62 FR 27191, May 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and distributors, including importers, to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions undertaken by device manufacturers and distributors, including importers, to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

(2) Market withdrawals as defined in § 806.2(h).

(3) Routine servicing as defined in § 806.2(k).

(4) Stock recoveries as defined in § 806.2(l).

§ 806.2 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Agency" or "FDA" means the Food and Drug Administration.

(c) "Consignee" means any person or firm that has received, purchased, or used a device subject to correction or removal.

(d) "Correction" means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.

(e) “Correction or removal report number” means the number that uniquely identifies each report submitted.

(f) “Distributor” means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(g) “Manufacturer” means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(h) “Market withdrawal” means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.

(i) “Removal” means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

(j) “Risk to health” means

(1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

(2) That use of, or exposure to, the product may cause temporary or medi-

cally reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

(k) “Routine servicing” means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

(l) “Stock recovery” means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

Subpart B—Reports and Records

§ 806.10 Reports of corrections and removals.

(a) Each device manufacturer, importer, or distributor shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or distributor if the correction or removal was initiated:

(1) To reduce a risk to health posed by the device; or

(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).

(b) The manufacturer, importer, or distributor shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. The report shall be submitted to the appropriate FDA district office listed in § 5.115 of this chapter. A foreign manufacturer or owner or operator of devices must submit reports of corrective or removal actions.