

**§ 806.30**

(b) Records of corrections and removals not required to be reported to FDA under §806.10 shall contain the following information:

(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.

(2) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.

(5) A copy of all communications regarding the correction or removal.

(c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42233, Aug. 7, 1998]

**§ 806.30 FDA access to records.**

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

[63 FR 42233, Aug. 7, 1998]

**§ 806.40 Public availability of reports.**

(a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

**21 CFR Ch. I (4-1-03 Edition)**

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under §20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under §20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under §20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

**PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES**

**Subpart A—General Provisions**

Sec.  
807.3 Definitions.

**Subpart B—Procedures for Device Establishments**

- 807.20 Who must register and submit a device list?
- 807.21 Times for establishment registration and device listing.
- 807.22 How and where to register establishments and list devices.
- 807.25 Information required or requested for establishment registration and device listing.
- 807.26 Amendments to establishment registration.
- 807.30 Updating device listing information.
- 807.31 Additional listing information.
- 807.35 Notification of registrant.
- 807.37 Inspection of establishment registration and device listings.
- 807.39 Misbranding by reference to establishment registration or to registration number.

**Subpart C—Registration Procedures for Foreign Device Establishments**

807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

**Subpart D—Exemptions**

807.65 Exemptions for device establishments.