

§ 821.50

21 CFR Ch. I (4–1–08 Edition)

(6) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(7) When applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(c)(1) A multiple distributor shall keep written records of the following each time such device is distributed for use by a patient:

(i) The lot number, batch number, or model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(ii) The name, address, telephone number, and social security number (if available) of the patient using the device;

(iii) The location of the device, unless not released by the patient under § 821.55(a);

(iv) The date the device was provided for use by the patient;

(v) The name, address, and telephone number of the prescribing physician;

(vi) The name, address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) When applicable, the date the device was permanently retired from use or otherwise permanently disposed of.

(2) Except as required by order under section 518(e) of the act, any person who is a multiple distributor subject to the recordkeeping requirement of paragraph (c)(1) of this section shall, within 5 working days of a request from the manufacturer or within 10 working days of a request from FDA for the information identified in paragraph (c)(1) of this section, provide such information to the manufacturer or FDA.

(d) A distributor, final distributor, or multiple distributor shall make any records required to be kept under this part available to the manufacturer of the tracked device for audit upon written request by an authorized representative of the manufacturer.

(e) A distributor, final distributor, or multiple distributor may petition for

an exemption or variance from one or more requirements of this part according to the procedures in § 821.2.

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

Subpart D—Records and Inspections

§ 821.50 Availability.

(a) Manufacturers, distributors, multiple distributors, and final distributors shall, upon the presentation by an FDA representative of official credentials and the issuance of Form FDA 482 at the initiation of an inspection of an establishment or person under section 704 of the act, make each record and all information required to be collected and maintained under this part and all records and information related to the events and persons identified in such records available to FDA personnel.

(b) Records and information referenced in paragraph (a) of this section shall be available to FDA personnel for purposes of reviewing, copying, or any other use related to the enforcement of the act and this part. Records required to be kept by this part shall be kept in a centralized point for each manufacturer or distributor within the United States.

[58 FR 43447, Aug. 16, 1993, as amended at 65 FR 43690, July 14, 2000]

§ 821.55 Confidentiality.

(a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient's name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.

(b) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with § 20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(c) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to

a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

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

§ 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

PART 822—POSTMARKET SURVEILLANCE

Subpart A—General Provisions

Sec.

- 822.1 What does this part cover?
- 822.2 What is the purpose of this part?
- 822.3 How do you define the terms used in this part?
- 822.4 Does this part apply to me?

Subpart B—Notification

- 822.5 How will I know if I must conduct postmarket surveillance?
- 822.6 When will you notify me that I am required to conduct postmarket surveillance?
- 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

Subpart C—Postmarket Surveillance Plan

- 822.8 When, where, and how must I submit my postmarket surveillance plan?
- 822.9 What must I include in my submission?
- 822.10 What must I include in my surveillance plan?
- 822.11 What should I consider when designing my plan to conduct postmarket surveillance?

- 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?
- 822.13 [Reserved]
- 822.14 May I reference information previously submitted instead of submitting it again?
- 822.15 How long must I conduct postmarket surveillance of my device?

Subpart D—FDA Review and Action

- 822.16 What will you consider in the review of my submission?
- 822.17 How long will your review of my submission take?
- 822.18 How will I be notified of your decision?
- 822.19 What kinds of decisions may you make?
- 822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?
- 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?
- 822.22 What recourse do I have if I do not agree with your decision?
- 822.23 Is the information in my submission considered confidential?

Subpart E—Responsibilities of Manufacturers

- 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?
- 822.25 What are my responsibilities after my postmarket surveillance plan has been approved?
- 822.26 If my company changes ownership, what must I do?
- 822.27 If I go out of business, what must I do?
- 822.28 If I stop marketing the device subject to postmarket surveillance, what must I do?

Subpart F—Waivers and Exemptions

- 822.29 May I request a waiver of a specific requirement of this part?
- 822.30 May I request exemption from the requirement to conduct postmarket surveillance?

Subpart G—Records and Reports

- 822.31 What records am I required to keep?
- 822.32 What records are the investigators in my surveillance plan required to keep?
- 822.33 How long must we keep the records?
- 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?