

Food and Drug Administration, HHS

§ 822.3

- 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?

- 822.35 Can you inspect my manufacturing site or other sites involved in my postmarket surveillance plan?
- 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?
- 822.37 Under what circumstances would you inspect records identifying subjects?
- 822.38 What reports must I submit to you?

AUTHORITY: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

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Subpart A—General Provisions

§ 822.1 What does this part cover?

This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year; or

(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the act and this part, your device is considered misbranded under section 502(t)(3) of the act and you are in violation of section 301(q)(1)(C) of the act.

§ 822.2 What is the purpose of this part?

The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

§ 822.3 How do you define the terms used in this part?

Some of the terms we use in this part are specific to postmarket surveillance and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation

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of the law. This section of the part defines the following terms:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., as amended.

(b) *Designated person* means the individual who conducts or supervises the conduct of your postmarket surveillance. If your postmarket surveillance plan includes a team of investigators, as defined below, the designated person is the responsible leader of that team.

(c) *Device failure* means a device does not perform or function as intended, and includes any deviation from the device's performance specifications or intended use.

(d) *General plan guidance* means agency guidance that provides information about the requirement to conduct postmarket surveillance, the submission of a plan to us for approval, the content of the submission, and the conduct and reporting requirements of the surveillance.

(e) *Investigator* means an individual who collects data or information in support of a postmarket surveillance plan.

(f) *Life-supporting or life-sustaining device used outside a device user facility* means that a device is essential to, or yields information essential to, the restoration or continuation of a bodily function important to the continuation of human life and is used outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. A physician's office is not a device user facility.

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

(h) *Postmarket surveillance* means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.

(i) *Prospective surveillance* means that the subjects are identified at the beginning of the surveillance and data or other information will be collected from that time forward (as opposed to retrospective surveillance).

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

(k) *Specific guidance* means guidance that provides information regarding postmarket surveillance for specific types or categories of devices or specific postmarket surveillance issues. This type of guidance may be used to supplement general guidance and may address such topics as the type of surveillance approach that is appropriate for the device and the postmarket surveillance question, sample size, or specific reporting requirements.

(l) *Surveillance question* means the issue or issues to be addressed by the postmarket surveillance.

(m) *Unforeseen adverse event* means any serious adverse health consequence that either is not addressed in the labeling of the device or occurs at a rate higher than anticipated.

§ 822.4 Does this part apply to me?

If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;

(b) The device is intended to be implanted in the human body for more than 1 year; or

(c) The device is intended to be used to support or sustain life and to be used outside a user facility.

Subpart B—Notification

§ 822.5 How will I know if I must conduct postmarket surveillance?

We will send you a letter (the postmarket surveillance order) notifying you of the requirement to conduct postmarket surveillance. Before we send the order, or as part of the order, we may require that you submit