

## § 822.10

- (7) Product codes and a list of all relevant model numbers; and
- (8) Indications for use and claims for the device;
  - (b) Postmarket surveillance plan;
  - (c) Designated person information;
    - (1) Name, address, and telephone number; and
    - (2) Experience and qualifications.

### § 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:

- (a) The plan objective(s) addressing the surveillance question(s) identified in our order;
- (b) The subject of the study, e.g., patients, the device, animals;
- (c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;
- (d) The surveillance approach or methodology to be used;
- (e) Sample size and units of observation;
- (f) The investigator agreement, if applicable;
- (g) Sources of data, e.g., hospital records;
- (h) The data collection plan and forms;
- (i) The consent document, if applicable;
- (j) Institutional Review Board information, if applicable;
- (k) The patient followup plan, if applicable;
- (l) The procedures for monitoring conduct and progress of the surveillance;
- (m) An estimate of the duration of surveillance;
- (n) All data analyses and statistical tests planned;
- (o) The content and timing of reports.

### § 822.11 What should I consider when designing my plan to conduct postmarket surveillance?

You must design your surveillance to address the postmarket surveillance question identified in the order you received. You should consider what, if any, patient protection measures should be incorporated into your plan. You should also consider the function, operating characteristics, and intended

## 21 CFR Ch. I (4–1–03 Edition)

use of your device when designing a surveillance approach.

### § 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's Web site and from the Center for Devices and Radiological Health, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Dr., Rockville, MD 20850. Guidance documents represent our current interpretation of, or policy on, a regulatory issue. They do not establish legally enforceable rights or responsibilities and do not legally bind you or FDA. You may choose to use an approach other than the one set forth in a guidance document, as long as your alternative approach complies with the relevant statutes (laws) and regulations. If you wish, we will meet with you to discuss whether an alternative approach you are considering will satisfy the requirements of the act and regulations.

### § 822.13 [Reserved]

### § 822.14 May I reference information previously submitted instead of submitting it again?

Yes, you may reference information that you have submitted in premarket submissions as well as other postmarket surveillance submissions. You must specify the information to be incorporated and the document number and pages where the information is located.

### § 822.15 How long must I conduct postmarket surveillance of my device?

The length of postmarket surveillance will depend on the postmarket surveillance question identified in our order. We may order prospective surveillance for a period up to 36 months; longer periods require your agreement. If we believe that a prospective period of greater than 36 months is necessary to address the surveillance question, and you do not agree, we will use the

Medical Devices Dispute Resolution Panel to resolve the matter. You may obtain guidance regarding dispute resolution procedures from the Center for Devices and Radiological Health's (CDRH) Web site ([www.fda.gov/cdrh/resolvingdisputes/ombudsman.html](http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html)) and from the CDRH Facts-on-Demand system (800-899-0381 or 301-827-0111, document number 1121). The 36-month period refers to the surveillance period, not the length of time from the issuance of the order.

Then, in accordance with the law, we must determine whether the designated person has appropriate qualifications and experience to conduct the surveillance and whether the surveillance plan will result in the collection of useful data that will answer the surveillance question.

**Subpart D—FDA Review and Action**

**§ 822.16 What will you consider in the review of my submission?**

First, we will determine that the submission is administratively complete.

**§ 822.17 How long will your review of my submission take?**

We will review your submission within 60 days of receipt.

**§ 822.18 How will I be notified of your decision?**

We will send you a letter notifying you of our decision and identifying any action you must take.

**§ 822.19 What kinds of decisions may you make?**

If your plan:	Then we will send you:	And you must:
(a) Should result in the collection of useful data that will address the postmarket surveillance question	An approval order, identifying any specific requirements related to your postmarket surveillance	Conduct postmarket surveillance of your device in accordance with the approved plan
(b) Should result in the collection of useful data that will address the postmarket surveillance question after specific revisions are made or specific information is provided	An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved	Revise your postmarket surveillance submission to address the concerns in the approvable letter and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
(c) Does not meet the requirements specified in this part	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
(d) Is not likely to result in the collection of useful data that will address the postmarket surveillance question	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit

**§ 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?**

The failure to have an approved postmarket surveillance plan or failure to conduct postmarket surveillance in accordance with the approved plan constitutes failure to comply with section 522 of the act. Your failure would be a prohibited act under section

301(q)(1)(C) of the act, and your device would be misbranded under section 502(t)(3) of the act. We have the authority to initiate actions against products that are adulterated or misbranded, and against persons who commit prohibited acts. Adulterated or misbranded devices can be seized. Persons who commit prohibited acts can be enjoined from committing such acts, required to pay civil money penalties, or prosecuted.