

**§ 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<br>(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 approval order, identifying any specific requirements related to your postmarket surveillance<br>An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved | Conduct postmarket surveillance of your device in accordance with the approved plan<br>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.

**§ 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?**

You must receive our approval in writing before making changes in your plan that will affect the nature or validity of the data collected in accord-

ance with the plan. To obtain our approval, you must submit three copies of the request to make the proposed change and revised postmarket surveillance plan to the applicable address listed in § 822.8. You may reference information already submitted in accordance with § 822.14. In your cover letter, you must identify your submission as a supplement and cite the unique document number that we assigned in our acknowledgment letter for your original submission, specifically identify the changes to the plan, and identify the reasons and justification for making the changes. You must report changes in your plan that will not affect the nature or validity of the data collected in accordance with the plan in the next interim report required by your approval order.

**§ 822.22 What recourse do I have if I do not agree with your decision?**

(a) If you disagree with us about the content of your plan or if we disapprove your plan, or if you believe there is a less burdensome approach that will answer the surveillance question, you may request review of our decision by:

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(1) Requesting a meeting with the Director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), who generally issues the order for postmarket surveillance;

(2) Seeking internal review of the order under §10.75 of this chapter;

(3) Requesting an informal hearing under part 16 of this chapter; or

(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site.

[67 FR 38887, June 6, 2002, as amended at 72 FR 17400, Apr. 9, 2007]

### § 822.23 Is the information in my submission considered confidential?

We consider the content of your submission confidential until we have approved your postmarket surveillance plan. After we have approved your plan, the contents of the original submission and any amendments, supplements, or reports may be disclosed in accordance with the Freedom of Information Act. We will continue to protect trade secret and confidential commercial information after your plan is approved. We will not disclose information identifying individual patients. You may wish to indicate in your submission which information you consider trade secret or confidential commercial.

## Subpart E—Responsibilities of Manufacturers

### § 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?

You must submit your plan to conduct postmarket surveillance to us within 30 days from receipt of the order (letter) notifying you that you are required to conduct postmarket surveillance of a device.

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### § 822.25 What are my responsibilities after my postmarket surveillance plan has been approved?

After we have approved your plan, you must conduct the postmarket surveillance of your device in accordance with your approved plan. This means that you must ensure that:

(a) Postmarket surveillance is initiated in a timely manner;

(b) The surveillance is conducted with due diligence;

(c) The data identified in the plan is collected;

(d) Any reports required as part of your approved plan are submitted to us in a timely manner; and

(e) Any information that we request prior to your submission of a report or in response to our review of a report is provided in a timely manner.

### § 822.26 If my company changes ownership, what must I do?

You must notify us within 30 days of any change in ownership of your company. Your notification should identify any changes to the name or address of the company, the contact person, or the designated person (as defined in §822.3(b)). Your obligation to conduct postmarket surveillance will generally transfer to the new owner, unless you and the new owner have both agreed that you will continue to conduct the surveillance. If you will continue to conduct the postmarket surveillance, you still must notify us of the change in ownership.

### § 822.27 If I go out of business, what must I do?

You must notify us within 30 days of the date of your decision to close your business. You should provide the expected date of closure and discuss your plans to complete or terminate postmarket surveillance of your device. You must also identify who will retain the records related to the surveillance (described in subpart G of this part) and where the records will be kept.

### § 822.28 If I stop marketing the device subject to postmarket surveillance, what must I do?

You must continue to conduct postmarket surveillance in accordance