

§ 822.16

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/ombudsman/*). The 36-month period refers to the surveillance period, not the length of time from the issuance of the order.

[72 FR 17400, Apr. 9, 2007]

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.

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.

§ 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: |
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| (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,