

## § 822.25

(letter) notifying you that you are required to conduct postmarket surveillance of a device. The manufacturer shall commence surveillance not later than 15 months after the day the order was issued.

[88 FR 16880, Mar. 21, 2023]

### **§ 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

## 21 CFR Ch. I (4–1–25 Edition)

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 with your approved plan even if you no longer market the device. You may request that we allow you to terminate postmarket surveillance or modify your postmarket surveillance because you no longer market the device. We will make these decisions on a case-by-case basis, and you must continue to conduct the postmarket surveillance unless we notify you that you may stop your surveillance study.

## **Subpart F—Waivers and Exemptions**

### **§ 822.29 May I request a waiver of a specific requirement of this part?**

You may request that we waive any specific requirement of this part. You may submit your request, with supporting documentation, separately or as a part of your postmarket surveillance submission to the address in § 822.8.

### **§ 822.30 May I request exemption from the requirement to conduct postmarket surveillance?**

You may request exemption from the requirement to conduct postmarket surveillance for your device or any specific model of that device at any time. You must comply with the requirements of this part unless and until we grant an exemption for your device. Your request for exemption must explain why you believe we should exempt the device or model from postmarket surveillance. You should demonstrate why the surveillance question does not apply to your device or does not need to be answered for the device for which you are requesting exemption. Alternatively, you may provide information that answers the surveillance question for your device, with supporting documentation, to the address in § 822.8.