Food and Drug Administration, HHS

§ 822.9 Subpart C—Postmarket Surveillance Plan

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B, Ammendale Rd., Beltsville, MD 20705–1266. For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

[75 FR 20915, Apr. 22, 2010]

§ 822.9 What must I include in my submission?

Your submission must include the following:

(a) Organizational/administrative information:
   (1) Your name and address;
   (2) Generic and trade names of your device;
   (3) Name and address of the contact person for the submission;
   (4) Premarket application/submission numbers for your device;

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health’s (CDRH’s) Web site (http://www.fda.gov/cdrh/ombudsman/dispute.html).

[67 FR 38887, June 6, 2002, as amended at 72 FR 17399, Apr. 9, 2007]