Food and Drug Administration, HHS

§ 822.6 When will you notify me that I am required to conduct postmarket surveillance?

We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.

§ 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;
   (5) Table of contents identifying the page numbers for each section of the submission;
   (6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);

(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]