

Appendix C: General Overview of Section 522 Studies

Postmarket Surveillance Studies Under Section 522

Postmarket surveillance under section 522 of the Act is one means by which the FDA can obtain additional safety and/or effectiveness data for a device after it has been cleared through the 510(k) process or approved through a PMA, humanitarian device exemption (HDE), or product development plan (PDP) process. However, postmarket surveillance is not a substitute for obtaining the necessary premarket information to support 510(k) clearance or PMA, HDE, or PDP approval.

Statutory Criteria

Section 522 of the Act, 21 U.S.C. 360l, authorizes the FDA to require postmarket surveillance in the following instances:

- a class II or class III device for which failure of the device would be reasonably likely to have a serious adverse health consequence. (Section 522(a)(1)(A)(i) of the Act);
- a class II or class III device expected to have significant use in pediatric populations. (Section 522(a)(1)(A)(ii) of the Act);
- a class II or class III device intended to be implanted in the human body for more than one year. (Section 522(a)(1)(A)(iii)(I) of the Act); and
- a class II or class III device intended to be a life-sustaining or life-supporting device used outside of a user facility. (Section 522(a)(1)(A)(iii)(II) of the Act).

One or more of the criteria above need to be met for section 522 postmarket surveillance to be considered by the FDA.

Postmarket Surveillance Study Process

The Center for Devices and Radiological Health (CDRH) may identify device issues that are appropriate for studying in a postmarket surveillance study at any point during the life cycle of the device. Such issues may be identified through a variety of sources including analysis of adverse event reports, a recall or corrective action, post-approval study data, review of premarket data, reports from other governmental authorities, or review of scientific literature.

The device issue identified is discussed by a cross-Center team with the ultimate goal of making a recommendation as to whether or not a 522 order should be issued to address a public health question. If an order for postmarket surveillance under section 522 is issued, then the order will identify the premarket submission(s) involved (i.e., 510(k), PMA, PDP, or HDE), the public health question(s), the rationale for the 522 order, and study design recommendations to assist the manufacturer in preparing the postmarket surveillance plan.

The FDA must approve the postmarket surveillance study plan prior to study commencement.

Postmarket Surveillance Study Plans

In general, section 522(b)(1) of the act authorizes the FDA to order prospective postmarket surveillance for a duration of up to 36 months unless the manufacturer and the FDA agree to extend that timeframe. Alternative study designs (e.g., not prospective surveillance) may be recommended by the FDA or proposed by the sponsor.

The elements to include in a postmarket surveillance study plan are provided below:

- background (e.g., regulatory history, brief description of device, indications for use)
- purpose of study (i.e., public health question(s) from 522 order)

- study objectives and hypotheses
- study design
- study population (including subject inclusion and exclusion criteria and definition and source of comparator group)
- sample size calculation (statistically justified and based on study hypothesis)
- primary and secondary endpoints (including definitions for study endpoints, success criteria, list of expected adverse events/complications, standard operating procedures for a determination of relatedness with the device and/or the procedure)
- length of follow-up, follow-up schedule, description of baseline and follow-up assessments
- description of data collection procedures (including recruitment plans, enrollment targets, plans to minimize losses to follow-up, follow-up rate targets, quality assurance, and control)
- statistical analysis
- data collection forms, informed consent forms, and IRB approval forms
- reporting requirements for interim and final reports
- study milestones/timeline elements

Monitoring of Postmarket Surveillance Studies

An interim and final reporting schedule is required as part of the study plan. After review of each 522 submission, the FDA determines study status with ongoing studies determined to be “Progress Adequate” or “Progress Inadequate” based on meeting milestones, enrollment schedule, follow-up rates, and endpoint evaluation.

After approval of the study plan, the contents of the original submission and any amendments, supplements or reports may be disclosed in accordance with the Freedom of Information (FOI) Act. The FDA continues to protect trade secret and commercial confidential information, as well as any personal privacy information for patients.

In addition, to increase transparency to our stakeholders, including consumers, physicians, and industry, the FDA posts information about postmarket surveillance studies on the 522 webpage (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm>). This information is posted in compliance with applicable disclosure statutes and regulations.