Draft Guidance for Industry and Food and Drug Administration Staff

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Procedures for Handling Section 522 Postmarket Surveillance Studies

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
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You should submit comments and suggestions regarding this draft document within **90** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Mary Beth Ritchey at 301-796-6638 or via email at MaryElizabeth.Ritchey@fda.hhs.gov.

When final, this document will supersede "Guidance for Industry and FDA Staff; Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act" issued on April 27, 2006

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Division of Epidemiology

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. Please use the document number **1754** to identify the guidance you are requesting.

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Draft Guidance for Industry and Food and Drug Administration Staff

Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

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

Section 307 of the FDA Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) amended section 522 of the act by adding class II and class III devices expected to have significant use in pediatric populations as a category of devices potentially subject to a postmarket surveillance order, authorizing the agency to order postmarket surveillance for durations longer than 36 months and as a condition of clearance or approval for devices within this category, and adding a dispute resolution provision.

This guidance document is intended to assist those subject to section 522 postmarket surveillance imposed by FDA by providing:

- an overview of section 522 of the act,

- procedural information on how to fulfill 522 obligations[1], and

- recommendations on the format, content, and review of postmarket surveillance study submissions.

Substantive additions to the 2006 version of this guidance document include: (1) guidance regarding the pediatric criterion added by section 307 of FDAAA; (2) recommendations for the content of postmarket surveillance study submissions, consistent with previous FDA requests; (3) descriptions of study status categories that more precisely indicate study progress and the adequacy of the data; and (4) updated procedures based on the transfer of the program area to Division of Epidemiology (DEPI), Office of Surveillance and Biometrics (OSB).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Legal Background

A. Statutory Criteria

Section 522 of the act, 21 U.S.C. 360l, authorizes 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 FDA.

[1] Refer to 21 CFR part 822 for the full set of postmarket surveillance regulations. This guidance document focuses on only some of the procedural regulations.

B. Considerations Regarding Pediatric Population Provisions

As stated above, FDAAA amended the scope of section 522 postmarket surveillance by authorizing postmarket surveillance for class II and III devices that are "expected to have a significant use in pediatric populations." This provision is not limited to devices labeled for pediatric uses; accordingly, FDA may use this authority to order surveillance of devices expected to have significant off label use in pediatric populations. The new provisions added by FDAAA also authorize the agency to order postmarket surveillance as a condition of clearance or approval for devices expected to have significant pediatric use.

FDAAA also states that any "pediatric postmarket surveillance required under section 522" is considered to be an "applicable device clinical trial" under section 402(j)(1)(A)(ii) of the Public Health Service Act (PHS Act) (42 USC 282(j)(1)(A)(ii)). As such, the pediatric postmarket surveillance study must be in compliance with the registration and results submission requirements of section 402(j) of the PHS Act (42 USC 282). Additional information on these requirements can be found at http://clinicaltrials.gov/ct2/invest and http://prsinfo.clinicaltrials.gov/.

C. Postmarket Surveillance Study Duration

In general, section 522(b)(1) of the act authorizes FDA to order prospective postmarket surveillance for a duration of up to 36 months unless the manufacturer and FDA agree to extend that timeframe. However, FDAAA added section 522(b)(2) to the act, which authorizes FDA to require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations, if such period is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device. FDA will work with the sponsor to determine the appropriate timeframe for a pediatric study.

3. Pre-522 Postmarket Surveillance Process

A. Identification of Issue

CDRH staff 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.

Examples of situations that may raise postmarket questions, during both the premarket and postmarket periods, are listed below.

- We may order postmarket surveillance to confirm the nature, severity, or frequency of suspected problems reported in adverse event reports or in the published literature.

- We may order postmarket surveillance to obtain more experience with a change from hospital use to use in the home or other environment or with new patient populations.

- We may order postmarket surveillance to address long term or infrequent safety and effectiveness issues of implantable and other devices for which the premarket testing provided only limited information. For example, premarket evaluation of the device may have been based on surrogate markers. Once the device is actually marketed, postmarket surveillance may be appropriate to assess the effectiveness of the device in detecting or treating the disease or condition, rather than the surrogate. Data collected during postmarket surveillance may include rates of malfunction or failure of a device intended for long-term use or incidents of latent sequelae resulting from device use.

- We may order postmarket surveillance to better define the association between problems and devices when unexpected or unexplained serious adverse events occur after a device is marketed, if there is a change in the nature of serious adverse events (e.g., severity), or if there is an increase in the frequency of serious adverse events.

B. Team Review of Issue

The device issue identified in Section 3A above is brought to the 522 Team Lead who then establishes a cross-Center team (i.e., pre-522 team) to review the issue in more depth. The pre-522 team discusses numerous elements with the ultimate goal of making a recommendation to the DEPI Division Director and OSB Director as to whether or not a 522 order should be issued to address a public health question.

Some of the elements discussed by the pre-522 team include:

- Are the statutory criteria met?

- What is the public health question? The delineation of the public health question is the most important element discussed by the team.

- What is the public health question based on? It should be based on CDRH evaluation of currently available data. Examples include but are not limited to: theoretical scientific/medical concern from review of premarket submission, and observed issues from the premarket data, a recall, MDRs, case studies, literature, or other source.

- Is the public health issue sponsor-specific, device-specific, or device type-specific?

- For a device for which a condition of clearance is being considered, can and should the public health question be addressed premarket rather than as part a 522 study?

- Is there any other source of data (e.g., MDR review, literature) or action (e.g., revised labeling, public health notice, recall), or a combination thereof, that may be used to address the public health question?

- Does another ongoing study (e.g., PMA post-approval study) address the public health question?

- What type(s) of 522 study design(s) should be recommended? Feasibility and timeliness of the different types of postmarket surveillance should be considered.

- What combination of efforts should be considered to address the public health question? In addition, what changes, if any, are being made with regard to the premarket review?

C. Issuance of 522 Order

An order for postmarket surveillance under section 522 will generally be issued by the OSB Director. The 522 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 you in preparing the postmarket surveillance plan. 21 CFR 822.5.

You must submit your postmarket surveillance plan within 30 days of receipt of the 522 order. 21 CFR 822.8.

4. Postmarket Surveillance Study Plans

Postmarket surveillance study plans are reviewed as an original submission and its amendments until the plan is approved. Subsequent changes to the plan after its approval are submitted and reviewed as postmarket surveillance study supplements. FDA will review all postmarket surveillance submissions and respond within 60 calendar days. 21 CFR 822.17.

A. Elements to Include in a Postmarket Surveillance Study Plan

The general and specific content for a postmarket surveillance study plan is outlined in 21 CFR 822.9 and 822.10. For clarity purposes, FDA describes the elements to include in a postmarket surveillance study plan in more detail as follows:

- 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, including:
    - expected date of study initiation
    - expected monthly number of study sites with IRB approvals
    - expected date of initiation of subject enrollment
    - expected number of subjects enrolled per month
    - expected date for subject enrollment completion
    - expected date to complete follow-up of all study participants
    - if applicable, information related to intermediate milestones (e.g., evaluation of surrogate endpoints in a study that also measures clinical benefits).

B. FDA and Sponsor Agreement on Study Plan

FDA will evaluate the proposed study plan to determine whether it is administratively complete and whether the surveillance plan will result in the collection of useful data that will answer the surveillance question(s). 21 CFR 822.16. FDA will then issue an approval order, an approvable letter requesting specific revisions or additional information needed before the plan can be approved, or a letter disapproving the proposed plan and explaining the reasons for disapproval. 21 CFR 822.19

If you disagree with FDA about the content of the plan or if we disapprove your plan, possible recourse options are described in 21 CFR 822.22. These include requesting a meeting with the Director, OSB; seeking internal review of FDA's decision under 21 CFR

10.75; requesting an informal hearing under 21 CFR Part 16; or requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

FDA developed this guidance document to help facilitate timely discussions with sponsors on postmarket surveillance study issues and challenges. We believe that early and ongoing interactions will afford optimal opportunities to agree on plans or other study issues and will be the primary method for resolving any issues. However, if you do not have an approved study plan within 6 months of issuance of the 522 order, the study status will be categorized as "Plan Overdue" on FDA's website. If you fail to meet the requirements for obtaining study plan approval within 12 months of the date of the 522 order, FDA will generally consider this to be a failure to comply with a requirement under section 522, which would render the device misbranded under section 502(t)(3) of the act.

C. Changes to an Approved Postmarket Surveillance Study Plan

If you wish to propose a change to an approved postmarket surveillance study plan, you must submit your request and the revised study plan for FDA review and approval. 21 CFR 822.21. Any submission involving a change to the approved study plan is tracked by FDA as a supplement to your 522 study.

D. Types of Postmarket Surveillance

We may order postmarket surveillance to address a wide variety of device-related public health questions. The table below describes different types of postmarket surveillance that may be used to address the public health question.

Type	**Definitions**
Randomized Clinical Trial	Prospective study comparing the effects of an intervention(s) against a control group. Subjects are assigned randomly to one of the study groups.
Prospective Cohort Study	A study in which the subjects in a defined population are followed prospectively in time to assess the occurrence of outcomes of interest as they occur. Such studies can include one or more groups defined in terms of their exposure to a device.
Retrospective Cohort Study	A study in which the subjects in a defined population are followed forward in time; however, unlike a prospective cohort, the data records documenting the device exposure and outcomes have been collected in the past relative to the time when the study is initiated. Such studies can also include one or more groups defined in terms of their exposure to a device.
Cross-Sectional Study	Study in which the presence or absence of an exposure and health outcome are assessed at the same point in time.
Enhanced Surveillance	Continued monitoring of the distribution and trends in the incidence of adverse events through ongoing, *passive* but systematic collection, analysis, and interpretation of data. The surveillance may be designed to collect information on events that are both MDR-reportable and MDR non-

Type	Definitions
	reportable adverse events or device complaints.
Active Surveillance	Continued monitoring of the distribution and trends in the incidence of adverse events through ongoing, *active* systematic collection, analysis, and interpretation of data. The surveillance may be designed to collect information on events that are both MDR-reportable and MDR non-reportable adverse events or device complaints.
Meta Analysis	Systematic review that combines the results of several studies that address a set of related research hypotheses. This is normally done by identification of a common measure of effect size, which is modeled using a form of meta-regression of the published or unpublished study data.
Prospective & Retrospective Study	A hybrid cohort study in which data are collected both retrospectively and prospectively.
Case Control Study	Study in which subjects are identified on the basis of the presence or absence of an outcome (cases) and compared to an appropriate comparison group. The proportions with the exposure of interest are compared.
Bench/Lab Study	A study that involves bench testing (e.g., wear testing, fatigue testing).
Animal Study	A study that involves animal testing (e.g., device or material implanted in animal).
Other Study Design	A study design that does not fit one of the other categories.

5. Interim Postmarket Surveillance Study Reports

An Interim Postmarket Surveillance Study Report is a written report to FDA on the status of the postmarket surveillance study prior to its completion.

A. Submission of Interim Postmarket Surveillance Study Report

21 CFR 822.38 requires that you submit interim and final reports as specified in your approved postmarket surveillance plan. Unless otherwise specified in the 522 order, we recommend you submit an Interim Postmarket Surveillance Study Status Report every 6 months for the first 2 years of the study and annually, thereafter, from the date of the 522 study plan approval or other negotiated starting date. We recommend you continue this reporting schedule until you have submitted the Final Postmarket Surveillance Study Report. We also recommend you indicate the appropriate time span on the interim report cover in bold letters (e.g., **6-Month Interim Postmarket Surveillance Study Report, 12-Month Interim Postmarket Surveillance Study Report)**. FDA intends to complete the review of your interim report and respond within 60 calendar days.

B. Sponsor's Reporting Status

Upon receipt of the interim report, FDA will determine your reporting status based on the agreed-upon schedule in the postmarket surveillance study plan. The reporting status categories appear in the table below.

Status	Definition
Report On Time	FDA has received the scheduled Interim or Final Postmarket Surveillance Study Report by the due date set in the agreed-upon schedule.
Report Overdue	FDA has not received the Interim or Final Postmarket Surveillance Study Report by the due date set in the agreed-upon schedule.
Report Overdue/Received	FDA has received the Interim or Final Postmarket Surveillance Study Report, although receipt was after the due date set in the agreed-upon schedule.

C. Evaluation of Interim Postmarket Surveillance Study Status Report

FDA epidemiologists from OSB intend to evaluate the Interim Postmarket Surveillance Study Report based on a wide range of criteria, including:

- the completeness of the report content
- the expected versus actual status of the study
- causes for and solutions to delays in study progress
- adherence to agreed-upon methodology and reasons for deviations from the methodology
- evaluation of information in the reports to address the public health question(s).

OSB will consult with ODE or OIVD and other offices as needed to ensure the data are assessed appropriately.

If we have questions regarding the data provided in the report, or if we believe the data are incomplete or insufficient, we may request additional information through the interactive review process and/or through a deficiency letter.

6. Final Postmarket Surveillance Study Reports

A Final Postmarket Surveillance Study Report is a written report of a terminated study or a completed postmarket surveillance study.

A. Submission of Final Postmarket Surveillance Study Report

We recommend the Final Postmarket Surveillance Study Report be submitted no later than three months after study completion, and should be prominently identified with **Final Postmarket Surveillance Study Report** at the top of the cover letter. We also recommend you identify the public health question(s) for which the report is being submitted if more than one study was used to address a particular 522 order. FDA intends to complete the review of your final report and respond within 90 calendar days.

B. Sponsor's Reporting Status

As with an interim report, upon receipt of the final report, FDA will determine your reporting status based on the agreed-upon schedule in the postmarket surveillance study plan.

C. Evaluation of Final Postmarket Surveillance Study Report

FDA recommends the Final Postmarket Surveillance Study Report describe the study methodology and results and explain how the study fulfills the 522 order. FDA epidemiologists from OSB will review the Final Postmarket Surveillance Study Report and determine if you have satisfied the 522 order. OSB will consult with ODE or OIVD and other offices as needed to ensure the data are assessed appropriately

If we conclude you have fulfilled your 522 obligations, FDA will send you a letter reflecting that decision.

However, if the results of the postmarket surveillance raise new issues or questions, additional actions may be required. We may, for example:

- request changes to the labeling of the device to reflect additional information learned from the postmarket surveillance;
- issue a new postmarket surveillance order to address new issues; or
- consider administrative or regulatory actions if necessary to protect the public health.

7. Content and Format of Interim and Final Postmarket Surveillance Study Reports

FDA's ability to adequately track and evaluate postmarket surveillance studies depends on the quality and timeliness of information you provide. The recommendations in this section are intended to ensure the reports you submit contain adequate information for us to identify the product being studied, the specific study being conducted, the status of that study, and, if applicable, the reasons for any delays or failures to complete the study.

FDA recommends that Postmarket Surveillance Study Reports (interim and final) include the information listed below, clearly identified and in separate sections.

A. General Information

FDA recommends this section contain:

- postmarket surveillance study application number;
- sponsor name and contact information (name of the individual or entity holding the approved PMA):
    - company name/institution name
    - street address
    - city
    - state/province
    - ZIP/postal code
    - phone number (include area code)
    - fax number (include area code)
    - contact name and title
    - contact e-mail address
- date of the 522 order;
- date of postmarket surveillance study plan approval and, if applicable, date(s) of approval of plan revision(s);
- device trade name(s); and
- device model number(s).

B. Submission Information

FDA recommends this section contain:

- date of submission;
- data included in this submission (choose one):
    - clinical study
    - laboratory study
    - animal study

- type of submission: (choose one)
    - Interim Postmarket Surveillance Study Report
    - Final Postmarket Surveillance Study Report
    - response to FDA correspondence for a deficient report or another reason (specify).

C. Study Information

FDA recommends this section contain (as applicable):

- purpose of the study, including study goals, objectives, and primary and secondary study endpoints;
- patient population being studied, including:
    - specific illness or condition
    - whether the study targets subpopulations (e.g., pediatric, geriatric)
    - total number of subjects to be studied
    - schedule of subject follow-up
- begin and end dates of period covered by the report;
- date of database closure for the report (should not exceed three months prior to the deadline for submission of report);
- summary of study progress milestones/timeline elements:
    - date of approval of the study plan
    - number of IRB approvals
    - number of clinical sites enrolled
    - number of clinical sites at which the study was initiated
    - completion date for enrollment of clinical sites
    - number of subjects enrolled (if applicable, this information should be presented for the entire subject population and for each subgroup)
    - subject accrual start date and subject accrual completion date
    - study targets: percentage of subjects reaching each designated study phase
    - comparison of target versus actual enrollment and follow-up
    - anticipated study completion date (i.e., complete follow-up of all study participants)

- if applicable, a rationale for not meeting the study milestones/timeline specified in the study plan and a revised study timeline[2];

- subject accountability data stratified by each follow-up timepoint for the entire population and for each subgroup. To limit the potential bias in safety and effectiveness data, you should make every effort to reduce the number of subjects lost-to-follow-up.
- if applicable, an explanation for:
    - subjects lost to follow-up, as well as any measure to minimize such future events
    - subject and physician-initiated discontinuations
    - any deaths, including reports from post-mortem examinations

- summary of safety and/or effectiveness data and an interpretation of study results to date.

8. Study Status Determination

After the review of a 522 submission, FDA will determine the status of the study using the categories in the table below.

Status	**Definition**
Plan Pending	FDA has not approved the study plan, and it has been less than 6 months since issuance of the order.
Plan Overdue	FDA has not approved the study plan, and it has been 6 months or more since issuance of the order.
Study Pending	The plan has been approved, but no subjects have been enrolled.
Progress Adequate	The study has begun, and the study progress is consistent with the plan (e.g., meeting enrollment schedule, follow-up rates, endpoints evaluated).
Progress Deficient	The study has begun, but the study progress is inconsistent with the plan (e.g., not meeting enrollment schedule, missing timepoint evaluations, poor follow-up rates, not all endpoints evaluated).
Completed	The sponsor has fulfilled the postmarket surveillance order and FDA has closed the study. This is a final study status
Terminated	The sponsor has not fulfilled or cannot fulfill the postmarket surveillance order (e.g., study questions are no longer relevant, sponsor withdraws premarket application, dataset cannot address 522 order), and, after all appropriate efforts to fulfill the order

[2] If a change in the study milestones/timeline could significantly impact the outcome of the postmarket surveillance study, then you should submit that revision as part of a 522 supplement for review and approval.

	have been exhausted, FDA has terminated the study. This is a final study status.
Other	The study status does not fit another category (e.g., change in ownership underway, redesigning device and need prior premarket clearance/approval to use in study, device has been cleared or approved but is not currently marketed). This is an interim study status.

9. Where to Submit Postmarket Surveillance Study Submissions

You should send three copies (one electronic and two paper copies) of all postmarket surveillance study submissions to:

522 Postmarket Surveillance Study Program
Division of Epidemiology
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave
WO66-4274
Silver Spring, MD 20993-0002

As we have explained in other contexts, "An electronic copy is an exact duplicate of a paper submission, created and submitted on a CD or DVD, accompanied by a copy of the signed cover letter and the complete original paper submission. An electronic copy is not an electronic submission." See "Electronic Copies for Pre-Market Submissions" Q&A, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm. Electronic copies of postmarket surveillance submissions accompanying the paper submission should be submitted to the address above.

10. Failure to Complete a Postmarket Surveillance Study

Failure or refusal to comply with a requirement under section 522 is a prohibited act under section 301(q)(1)(C) of the act, 21 U.S.C. 331(q)(1)(C), and renders the device misbranded under section 502(t)(3) of the act, 21 U.S.C. 352(t)(3). Please note that violations of sections 301(q)(1)(C) and 502(t)(3) may lead to enforcement actions including seizure of your product, injunction, prosecution, and/or civil money penalties. See 21 CFR 822.20. Under section 522(c), manufacturer may request review under section 562 of the act, 21 U.S.C. 360bbb-1, of any order or condition requiring postmarket surveillance under section 522.

There may be circumstances that make it impossible or inappropriate for you to complete a particular postmarket surveillance study. For instance, you may have instituted a voluntary

withdrawal or recall of the device from the market, thereby negating the need for the study. We recommend that you initiate early communication with FDA if you intend to terminate the study prior to fulfilling the postmarket surveillance study commitment.

Alternatively, if FDA determines the study will not answer or adequately address the questions in the order, for example because of the study design, because of study data inadequacies, or due to a discontinuation in marketing or manufacturing of the device, but the study objectives remain important, we may initiate termination of the original study and discuss establishing a new postmarket surveillance study commitment and schedule.

11. Public Disclosure of a Postmarket Surveillance Study

After approval of your plan, the contents of the original submission and any amendments, supplements or reports may be disclosed in accordance with the Freedom of Information Act. We will continue to protect trade secret and commercial confidential information, as well as any personal privacy information for patients. 21 CFR 822.23.

Any postmarket surveillance study that is an "applicable device clinical trial" as defined in section 402(j)(1)(A)(ii) of the PHS Act (42 USC 282(j)(1)(A)(ii)), added by Title VIII, FDAAA, must comply with registration and results submission requirements for such clinical trials. Certain information on clinical trials is publicly available on the www.ClinicalTrials.gov website. Additional information on these requirements can be found at http://clinicaltrials.gov/ct2/invest and http://prsinfo.clinicaltrials.gov/.

In addition, to increase transparency to our stakeholders, including consumers, physicians, and industry, FDA posts information about postmarket surveillance studies on our 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. Study details that may be posted include:

- postmarket surveillance study number
- applicant name
- device name
- medical specialty (e.g., cardiovascular, orthopedic)
- date of the 522 order
- study name
- plan approval date
- study population
- study status
- interim and final report schedule
- due date for interim and final report (based on agreed-upon schedule)

- FDA receipt date of interim and final report
- status category of interim and final report.

Additional study elements may be posted on FDA's website, as permitted by applicable disclosure statutes and regulations.