Guidance for Industry, Review Staff, and the Clinical Community

Guidance on Criteria and Approaches for Postmarket Surveillance

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Postmarket Surveillance Studies Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics

Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions may be submitted at any time for Agency consideration to Postmarket Surveillance Studies Branch, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, 1350 Piccard Drive (HFZ-543), Room 330Q, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Rachel E. Solomon at the address above or at (301) 594-0639.

Additional Copies

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CRITERIA AND APPROACHES FOR POSTMARKET SURVEILLANCE

The Food and Drug Administration Modernization Act of 1997 (FDAMA) modified postmarket surveillance (PS) requirements under section 522 of the Federal Food, Drug, and Cosmetic Act. Specifically, under FDAMA the Agency may:

> ". . . require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be –
>
> (1) implanted in the human body for more than one year, or
>
> (2) a life sustaining or life supporting device used outside a device user facility."

The Agency plans to use more specific non-binding criteria to exercise the discretion provided under this section of the Federal Food, Drug, and Cosmetic Act with greater consistency. This document presents an outline of criteria that the Agency intends to use routinely to implement postmarket surveillance under FDAMA. The criteria are general principles that will guide the Agency's decisions concerning postmarket surveillance. In general, it is these criteria that will be used to identify the products in the above categories for consideration of postmarket surveillance. The need for postmarket surveillance for any product will be established by problem assessment and supported with a described rationale for the study before issuance of the order.

This document is intended to provide guidance. It represents the Agency's current thinking; but does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The Agency initially solicited input on criteria for postmarket surveillance at a public meeting on Changes in Medical Device Tracking and Postmarket Surveillance Authority on January 15, 1998, in Gaithersburg, MD. Comments were received from consumer, clinical, and industry representatives. Additional comments from the public are invited and may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857, for 90 days following the date of publication in the Federal Register of the notice of availability of this guidance. After that date, comments and suggestions may be submitted at any time for Agency consideration to the Postmarket Surveillance Studies Branch, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, 1350 Piccard Drive (HFZ-543), Room 330Q, Rockville, MD 20850.

Criteria for Postmarket Surveillance

- Delineation of an important unanswered surveillance question about a marketed device.

Premarket testing cannot address all device-related concerns. While postmarket surveillance will not be used in lieu of adequate premarket testing, postmarket surveillance can serve to complement premarket data. Certain issues that arise during premarket evaluation of a device may be more appropriately addressed through data collection in the postmarket period rather than prior to approval/clearance for marketing. FDA will consider the potential to collect postmarket surveillance data to allow more rapid progress to market.

Surveillance questions also may be raised about a marketed device from a variety of sources, including spontaneous reports, product complaints, and published literature. In such cases, postmarket surveillance may be used to confirm the nature, severity, or frequency of suspected problems.

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

⇒ *New or expanded conditions of use for existing devices*

Postmarket surveillance may be used to augment premarket data to obtain more experience with change from hospital use to use in the home or other environment or with new patient populations.

⇒ *Significant changes in device characteristics (technology)*

Significant or developmental changes to device technology may also give rise to some questions that can be most appropriately addressed in the postmarket period. Changes in the technology of a device may also raise concerns about the duration of the effectiveness of the device which could be answered by postmarket surveillance. In these situations, postmarket surveillance, through collection of longer-term safety and effectiveness data, may augment premarket data and allow earlier marketing of new technologies without compromising the public health.

⇒ *Longer term follow-up or evaluation of rare events*

Postmarket Surveillance evaluation may be able to address longer term or less common safety and effectiveness issues of implantable and other devices that cannot be adequately assessed during the relatively short premarket testing period. For example, premarket evaluation of the device may have been based on surrogate markers and postmarket surveillance may be appropriate to assess the effectiveness of the device in detecting or treating the disease or condition, rather than the surrogate, once the device is actually marketed. Data collected during such 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.

⇒ *Public health concern(s) resulting from reported or suspected problems in marketed devices*

Examples of problems that may raise concerns include: change in the nature of serious adverse events (e.g., severity); increase in the frequency of serious adverse events; widespread less serious adverse reactions which may be associated with an unknown frequency of more serious events; or unexpected or unexplained deaths or serious injuries. In circumstances such as these, postmarket surveillance may be necessary to define the association between problems and devices and better understand what corrective action may be necessary.

- Ability of other postmarket mechanisms to address public health concerns raised by the surveillance question

  Consideration should be given to whether other mechanisms may address the question, such as postapproval requirements, MDR, quality systems requirements, field inspections, or special controls.

- Practicality of postmarket surveillance strategies

  Consideration should be given to the feasibility and timeliness of postmarket surveillance, and to the usefulness of data to be collected. For example, the relative value of postmarket surveillance for a given device may be influenced by the rate of device evolution. Postmarket surveillance may not be reasonable if FDA determines that the applicability of the results will be minimal by the time postmarket surveillance is completed.

- Priority of surveillance question, based on magnitude of risk

The Agency will assign higher priority for postmarket surveillance where a significant risk to public health has been identified or is suspected.

Approaches for Postmarket Surveillance

Postmarket surveillance may be used to address a wide variety of device-related public health questions. In general, the FDA intends that manufacturers use the most practical, least burdensome approach to produce a scientifically sound answer to the question to be addressed in postmarket surveillance. The following examples illustrate a range of surveillance methods and situations in which they might be appropriate. The examples should not be considered a comprehensive or prescriptive listing of possible approaches to postmarket surveillance.

- Detailed review of complaint history and scientific literature
  - ⇒ *Example: development of a complaint profile for a device with established record of clinical use with few unexpected adverse events, and there exist similar reports in the scientific literature.*

- Non-clinical testing of the device
  - ⇒ *Example: in vitro or animal evaluation of the device. May include explant analysis, testing of used devices to assess continued performance to specifications, or other laboratory-based testing.*

- Telephone or mail follow-up of a defined patient sample
  - ⇒ *Example: effectiveness of user training for a home-use device previously used only in the hospital setting; outcomes easily and reliably reportable directly by patient.*

- Use of existing secondary data sets, such as Medicare data
  - ⇒ *Example: for generic product types in common use, may address general issues such as device usage, survival, or repeat hospitalization. Such data sets may lack specificity regarding device identity or particular outcomes of interest. Utility determined by the parameters of the data set.*

- Use of registries, such as the Society for Angiography and Interventional Cardiology (SAIC) stent registry, or internal registries or tracking systems
  - ⇒ *Example: basic surveillance of device or disease outcomes. Often developed to record short-term experience or complications in device recipients, but may include longer term follow-up. Usefulness depends on representativeness of patients in registry and data captured.*

- Case-control study of patients implanted with or using devices
  - ⇒ *Example: suspected problems/disease conditions with a device also can exist without exposure to device. Comparing of cases and controls to quantify magnitude of risk posed by device exposure.*

- Consecutive enrollment studies
  - ⇒ *Example: assessment of outcomes following device exposure, to assess the frequency of problems based on clinical follow-up of patients.*

- Cross-sectional studies (multiple cohorts)
  - ⇒ *Example: assessment of device safety and/or effectiveness at designated time intervals post-surveillance plan initiation.*

- Non-randomized controlled cohort studies
  - ⇒ *Example: suspected problems reported to occur more often with one type of device where other devices/therapies exist; study needed to more accurately quantify risks and benefits to alternative device/therapy uses.*

- Randomized controlled trials
  - ⇒ *Example: a device approved for use with a broad indication. Following reports of adverse events in a sub-population with events similar to consequences of the disease in the sub-population, a trial is needed to evaluate the risk to benefit in the sub-population.*