Guidance On Procedures to Determine Application of Postmarket Surveillance Strategies

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

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Until May 26, 1998, comments and suggestions regarding this document should be submitted to Docket No. 98D-0106, 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 May 26, 1998, comments and suggestions may be submitted at any time for Agency consideration to Postmarket Surveillance Studies Branch, HFZ-543, 1350 Piccard Drive, Rockville, Maryland 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 **Laura Alonge at (301) 594-0648 or by e-mail at laa@cdrh.fda.gov.**

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

GUIDANCE[1] ON PROCEDURES TO DETERMINE APPLICATION OF POSTMARKET SURVEILLANCE STRATEGIES

OVERVIEW

- Device issue identified as candidate for postmarket surveillance
- Surveillance question developed; issue/concern and risks and benefits of the device discussed
- Device and surveillance question compared to criteria for various mechanisms (statutory as well as any criteria developed by CDRH)
- Available mechanisms for addressing the surveillance question examined, recommendation developed
- Postmarket surveillance strategy imposed

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INTRODUCTION

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA) and the Food and Drug Modernization Act (FDAMA) of 1997, provides the Center for Devices and Radiological Health (CDRH) with a number of postmarket tools to protect public health while continuing the availability of safe, effective medical devices. When a medical device is cleared for marketing, there may be important residual questions about the device that have not yet been answered. Postmarket issues may be identified through a variety of sources, including analysis of adverse event reports, a recall or corrective action, or reports from other governmental authorities or the scientific literature.

There are several areas that should be considered when establishing a postmarket strategy for a particular device or type of device. CDRH's general approach will be to identify the objective, the information that is needed to achieve this objective, and appropriate sources and mechanisms for obtaining this information.

The purpose of this guidance is to describe the procedures for invoking postmarket surveillance under section 522. We are establishing these procedures now, in part, because under FDAMA the agency must evaluate each suggested postmarket surveillance separately. This guidance document represents the agency's current thinking on invoking postmarket surveillance under section 522 as revised by FDAMA. It 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 feasible if such approach satisfies the requirements of the applicable statute, regulations, or both.

POSTMARKET STRATEGIES COMMITTEE (PSC)

A committee(s) will be established by the Director of OSB to consider and evaluate device-specific issues and available postmarket mechanisms and make recommendations for appropriate action. It will usually have participants from all affected Offices.

IDENTIFICATION OF DEVICE ISSUE

A device issue may be nominated for consideration by the PSC by anyone in CDRH (e.g., a reviewer in ODE, a lab scientist in OST) and forwarded with the concurrence of their Division Director. Once the Division Director has agreed that section 522 surveillance should be considered, the CDRH staff person will consult with the Postmarket Surveillance Studies Branch (PSSB) to develop the rationale statement for presentation to the PSC. This rationale statement will briefly summarize the hazard signal/concern, the applicable safety and

effectiveness (i.e., risks and benefits) information, the problem or issue, alternate strategies to resolve the concern, and the surveillance question to be addressed if postmarket surveillance is ordered.

EVALUATION OF DEVICE ISSUE

The PSSB will advise on whether the device and surveillance question meet the statutory criteria for postmarket surveillance under section 522 of the Food, Drug, and Cosmetic Act. The PSSB will also review the rationale statement in light of CDRH's discretion on imposing postmarket surveillance. The PSC will, in consultation with PSSB, review the proposal and evaluate the applicability of postmarket surveillance under section 522 for addressing the surveillance question, review the available approaches to address the identified concern, and make a recommendation to the Director of OSB. The Director of OSB, after providing the directors of OC, ODE, OST and OHIP, as appropriate to the issue, a chance to comment, will decide whether to impose postmarket surveillance under section 522. If the PSC has identified other postmarket mechanisms, the Director of OSB will refer these to the appropriate Office Director(s).

ORDERING POSTMARKET SURVEILLANCE

The OSB Director will generally issue the orders for postmarket surveillance under section 522. In cases where postmarket surveillance requirements under section 522 have been previously established for a device category, ODE may issue the orders as part of an approval order or a substantial equivalence determination. The order will contain the rationale for imposing postmarket surveillance under section 522, the Center's recommendations (if any) as to the type of data collection needed to address the concern and any other information available that may assist the manufacturer in preparing the postmarket surveillance plan. The PSSB will facilitate meetings with manufacturers to discuss specific surveillance objectives, appropriate surveillance methodologies, analytical methodologies, and reporting timeframes.

MONITORING

The PSSB, in a meeting of the program Office Directors and Center Director, will review, twice a year, the number of 522 orders, the status of studies and the reported results of studies to assist in analyzing the effectiveness of the various mechanisms for addressing postmarket issues.