GUIDANCE ON PROCEDURES FOR REVIEW OF POSTMARKET SURVEILLANCE SUBMISSIONS

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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-0107, 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, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, 1350 Piccard Drive, HFZ-543, 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 Daniel S. McGunagle **at (301) 594-0639 or dsm@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

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The decision to order postmarket surveillance (PS) will be made using the procedure described in the document "GUIDANCE ON PROCEDURES TO DETERMINE APPLICATION OF POSTMARKET SURVEILLANCE STRATEGIES."

This guidance[1] document on procedures for review describes the administrative procedures, responsibilities, obligations, and functions to be used when implementing postmarket surveillance of a medical device under the authority contained in Section 522 of the Act as amended by the Food and Drug Administration Modernization Act. We are establishing these procedures now, in part, because the SMDA requirement for Scientific and Technical Review Committees does not apply to postmarket surveillance ordered under FDAMA. This guidance document represents the Agency's current thinking on the above. 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 used if such approach satisfies the requirements of the applicable statute, regulations, or both.

1. Within 10 days of plan receipt, the Postmarket Surveillance Studies Branch (PSSB) lead (OSB staff member assigned to the task) will determine need for consulting reviews and distribute plan to any consultative reviewers (usually one to three). The CDRH Division that has MDR, compliance, premarket, or scientific expertise most relevant to (decision by Chief, PSSB) the postmarket surveillance issue will provide the technical lead for the postmarket surveillance effort. Other review resources may include OSB staff from Epidemiology, Biostatistics and Postmarket Surveillance Studies teams and other Center personnel.

2. The PSSB lead, in conjunction with the technical lead, will have the primary responsibility for submission review and authorship of any deficiency statements, review of the sponsor's deficiency responses and preliminary recommendation on surveillance plan approval. Other reviewers will be responsible for providing technical, scientific, statistical, regulatory, and public health review and input to the above processes, as appropriate. Input should be in the form of written reviews of submissions and attendance at meetings called by the technical lead. In cases where reviewers believe additional information is required, their written reviews should contain specifically worded deficiencies ready for direct, 'cut and paste,' insertion into a letter to

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the sponsor. Scientific/technical reviews should generally be completed and provided to PSSB within 30 days. Within 60 days of plan receipt, OSB will make the final decision on plan approval/disapproval.

3. After approval of the surveillance plan, the PSSB lead and technical lead will be responsible for determining whether or not the sponsor is conducting the surveillance in accordance with the approved plan and for evaluating the surveillance data (with consultation, as necessary).

4. OSB will provide document handling, administrative services, and postmarket regulatory review. This includes the preparation of final letters responding to submissions.

5. OSB is responsible for final decisions related to plan approval/disapproval, conduct of the surveillance and evaluation of surveillance data. All correspondence for postmarket surveillance will go out under Director, OSB final signature after the technical lead office signs-off on the document. The technical lead and consultant(s) will be responsible for obtaining supervisory concurrence by their Office.

6. The contents of the postmarket surveillance rationale statement will be used to determine the close out point of the surveillance. Once the questions or issues justifying the surveillance order have been addressed, the surveillance will be considered complete. If new issues or questions develop from the results of the surveillance, additional actions may be required. If the surveillance findings indicate that further action (i.e., continuation of the existing postmarket surveillance, a new postmarket surveillance, changes to the device or its labeling, some form of regulatory action, etc.) is indicated, the proper course of action will be determined at that time.

7. Updates will be given by the technical lead to OSB/PSSB staff and to the standing Postmarket Strategy Committee. These will be given most often at quarterly intervals unless the particular study warrants a higher level of vigilance with more rapid feedback to CDRH staff or management.

8. If the technical lead and consultants determine that the manufacturer has not conducted the PS in accordance with the approved plan, OSB and OC will work together and find appropriate enforcement strategies.