Premarket Notification - Consistency of Reviews #K89-1 (blue Book memo) (Text Only)

510(k) Memorandum #K89-1

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February 28, 1989

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Premarket Notification - Consistency of Reviews

I. PURPOSE OF THE GUIDANCE

This guidance document outlines methods for identifying important issues that require uniform treatment across the divisions of the Office of Device Evaluation, for developing guidance on these issues, and for ensuring proper implementation in the review of premarket notifications (510(k)) for the purpose of achieving a high level of consistency in the review process.

II. BACKGROUND

At the request of Congressman Henry Waxman, the United States General Accounting Office (GAO) conducted an extensive review of FDA's implementation of the premarket notification (510(k)) program. GAO was asked to identify any problems pertaining to both formal policies and the day-to-day operations of the program.

GAO first contacted FDA in October, 1986 to schedule an entry conference for the purpose of explaining what the study would encompass. The study continued until November, 1987 and the final GAO report to Congressman Waxman issued on September 21, 1988.

The final GAO report identified areas where improvement to the program could be made and included specific recommendations to Congress, the Department of Health and Human Services, and FDA. GAO recommended that FDA develop a mechanism to improve consistency of 510(k) reviews. In response to these recommendations, the ODE division directors met, discussed, and developed the guidance below.

III. MECHANISM TO IMPROVE CONSISTENCY OF 510(k) REVIEWS

A. Documentation: The Premarket Notification Coordinator will develop

guidance for the documentation of all 510(k) reviews, which will prompt the reviewer for answers to questions critical to decisions of substantial equivalence and critical to consistent applications of ODE guidance. Further, the guidance will prompt the reviewer to refer to other guidance documents in areas where ODE has established crosscutting guidance (e.g., toxicology, software, sterilization, etc.).

B. Crosscutting issue identification: At monthly management meeting of the ODE senior staff, time will be allotted for the specific purpose of identifying important issues that require uniform treatment. These issues may be scientific, regulatory, or administrative. Division directors will solicit input on important issues for consideration from their branch chiefs and staffs on a routine basis. The Premarket Notification Coordinator will also be responsible for identifying important crosscutting issues for consideration. Monthly meetings of all ODE branch chiefs will serve as another vehicle for identifying crosscutting issues and bringing them to the attention of ODE management. Identification of important issues will be based on personal observation, review of premarket notification decisions and supporting documentation, input from Center committees, input from outside organizations and special studies conducted at the request of the Director, ODE.

C. Implementation of new guidance procedures: When it is determined that new guidance is needed, they will be developed and disseminated by means such as:

1. Blue book memoranda;

2. Memoranda to review staff;

3. Senior management meetings with review staff;

4. Training sessions or workshops for supervisors and review staff; and

5. Other activities as deemed appropriate.

D. Monitoring the implementation: The division directors and branch chiefs have responsibility for monitoring the implementation of new

guidance within their respective organizations. The Premarket Notification Coordinator will monitor implementation across the divisions of ODE. The monthly senior staff management meetings and branch chief meetings will provide additional, informal opportunities for monitoring.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)