PMA Compliance Program #P91-3 (blue book memo) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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. This guidance will be updated in the next revision to include the standard elements of GGP's.

PMA Memorandum #P91-3

May 3, 1991

PMA Compliance Program

Purpose

The purpose of this guidance memorandum is to make available to ODE reviewers an interoffice agreement regarding Office of Device Evaluation (ODE)/Office of Compliance and Surveillance (OCS) roles in supporting the PMA compliance program. It outlines each office's responsibility for the implementation of the PMA compliance program.

Background

As part of an Agency-wide initiative to improve the premarket assessment of new products, the OCS with the cooperation of the ODE has developed a new compliance program entitled "Medical Device Premarket Approval Inspections." This compliance program was cleared by the Office of Regulatory Affairs on November 7, 1990. On April 15, 1991, the Office of Device Evaluation and the Office of Compliance and Surveillance entered into an interoffice agreement (attached) concerning the respective roles of ODE and OCS under this new compliance program. While the agreement does not have a direct impact on review divisions, it is important for all ODE managers and reviewers to understand our office responsibilities and to recognize the impact that the PMA compliance program has on the PMA evaluation process. It is for these reasons that I am requesting that you take a few moments to familiarize yourself with the content of the agreement.

Any questions from the regulated industry regarding the PMA compliance program, other than questions relating to ODE procedures and responsibilities, should be referred to OCS for resolution. If you have questions regarding any aspects of the interoffice agreement or how the agreement will impact upon the applications in your division, please see your division's PMA contact person in the Program Operations Staff.

Effective Date

This policy is effective immediately.

Acting Director, Office of Compliance and Surveillance (HFZ-300)

Interoffice Agreement Regarding ODE/OCS Roles in Supporting the PMA Compliance Program

As part of an Agency-wide initiative to improve the premarket assessment of new products, the Office of Compliance and Surveillance (OCS) with the cooperation of the Office of Device Evaluation (ODE) has developed a new compliance program entitled "Medical Device Premarket Approval Inspections." This compliance program was cleared by the Office of Regulatory Affairs on November 7, 1990. It directs the field to consider the extent to which the firm has established a formal quality assurance program, with emphasis on ensuring that the approved design is properly translated into specifications via process validation. If the compliance program is to operate satisfactorily, the ocs and the ode must provide administrative, technical support, and direction to the field.

Under the PMA regulation, sponsors are required to submit detailed information describing the manufacture of the PMA device. If this requirement was rigorously enforced, most PMA applications currently under review would be considered deficient. In the next few weeks, ODE will be sending to sponsors a document which will provide guidance outlining the information that must be included in the manufacturing sections of PMA applications. Although not formalized in the attached Interoffice Agreement, we have agreed to allow sponsors a 90-day grace period to adjust to the "new" requirements for manufacturing information.

Please review the attached agreement and indicate your concurrence/nonconcurrence.

Ronald M. Johnson

Attachment

INTEROFFICE AGREEMENT REGARDING ODE/OCS ROLES IN SUPPORTING THE PMA COMPLIANCE PROGRAM

On December 4, 1989, the Associate Commissioner for Regulatory Affairs, with the concurrence of the Compliance Policy Council, directed all Center Directors to develop and implement procedures, "to assure that new products are approved only after full consideration of field inspectional findings." One of the goals of this New Products Approval Action Plan required that CDRH develop a Premarket Approval Compliance Program, which would provide to the field guidance for assessing a sponsor's capability to manufacture a PMA device. The goal also required that the compliance program should be consistent with the new product approval compliance programs issued by the other centers in FDA.

The purpose of this document is to set forth the respective roles of the Office of Compliance and Surveillance (OCS) and the Office of Device Evaluation (ODE) in regard to the review of the manufacturing sections of premarket approval applications, premarket approval inspection reports and postmarket approval inspection reports.

ODE has the lead responsibility for the review of the entire PMA application. The role of OCS is to act as technical support in the manufacturing and quality assurance area. To fulfill that role, OCS conducts a prefiling review of the PMA manufacturing section to assure that it describes the manufacturing and quality assurance systems in sufficient detail to determine if a GMP program is established, issues inspection assignments to the field, and reviews the inspection reports to assure that the sponsors have the capability to manufacture the PMA device, and are in compliance with the requirements of the GMP regulation.

OFFICE OF DEVICE EVALUATION (ODE)

- ODE receives the PMA applications submitted by the sponsors. The applications are either original PMA applications, or PMA supplements.
- Within three days after completing the initial pre-filing revie of a PMA application, ODE will provide to OCS/DCP those sections of the application that pertain to manufacturing, labeling and device characteristics.

- When notified by OCS that the manufacturing sections of an application is inadequate, ODE will determine if it is necessary to contact the sponsor, via a Deficiency Letter, and request the missing manufacturing information. Upon receipt of such information, ODE will forward the information to OCS for review. If ODE decides that no Deficiency Letter is necessary, it will notify OCS.

- ODE will notify OCS within three days after filing a PMA application.

- ODE may, on its own initiative, choose to approve a PMA application without an evaluation of the manufacturing by OCS. If and when ODE anticipates such an approval, ODE will notify OCS immediately so that OCS can cancel any inspection assignment, and notify the district that the PMA will be approved without an inspection.

- In order to ensure continuity in reviews and inspectional coverage, ODE will provide to OCS PMA supplements describing changes in design and manufacturing, for use by the field during the post-approval inspections.

THE OFFICE OF COMPLIANCE AND SURVEILLANCE (OCS)

- Before ODE files an application, OCS will review the manufacturing, labeling, and appropriate device characteristics information to determine whether the application contains sufficient information for an evaluation of the sponsor's capability to manufacture the PMA device.

- OCS will notify ODE of significant deficiencies in the submission that may prohibit filing.

- OCS will review additional information submitted by a sponsor in response to a Deficiency Letter. If necessary, deficiencies will again be identified for ODE.

- OCS may conclude that a pre-approval inspection is required if any of the following conditions are found:

- It is determined from OCS's search of the GWQAP data base that an inspection of the facility has not taken place within the last two years.

- That an inspection was conducted, but did not cover a similar process and product.

- That an inspection was conducted and the district decision was VAI-3 or OAI.

o If OCS concludes that a pre-approval inspection is required, OCS will issue an inspection assignment to the district where the manufacturing facility is located, and will include with the assignment the complete manufacturing section, labeling information, and device characteristics package. OCS will issue the inspection assignment only after the PMA application has been filed by ODE.

o When OCS receives the Establishment Inspection Report (EIR) from the District, OCS will review the report and any district recommendations.

o Based upon the review, OCS will notify ODE that the manufacturing and quality assurance systems used for the PMA device and either approvable or not approvable. OCS will also send a "Feedback" letter to the District indicating CDRH's concurrence or nonconcurrence with the District's recommendation and identifying specific concerns to be followed up during the post-approval inspection.

o When no assignment for a pre-approval inspection is issued, OCS will forward a FAX memorandum to the appropriate District Director notifying the District that CDRH intends to approve the facility unless information to the contrary is received within 10 working days.

o After notification from ODE that the firm's PMA application is ready for final approval, OCS will be responsible for checking the OAI Alert database to confirm that the firm remains in compliance.

OCS will also notify the appropriate District when the PMA

application is ready for final approval.

- When receiving a response from the District Director advising that the facility under consideration is not approvable, or that approval should be delayed, OCS will issue a memorandum to ODE advising that the PMA should not be approved until the District's concerns are resolved.

- If the District's recommendation is other than approvable, OCS will decide what course of action to take regarding resolution of the District's concern.

- If ODE has received PMA supplements for changes in the design, labeling or manufacturing process, OCS will evaluate the adequacy of such changes and identify potential problems. OCS will relay the required information to the District as soon as possible for use in conducting post-approval inspections.

Upon receipt of the Post Approval EIR, OCS will review all comments made and notify the District and ODE of any regulatory action indicated.

Ann B. Holt, DVM

Concur Nonconcur Date

Robert L. Sheridan

Concur Nonconcur Date

Walter E. Gundaker

Concur Nonconcur Date

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)