Panel Review of Premarket Approval Applications #P91-2 (blue book memo) (Text Only)

The 21st Century Cures Act (Cures), signed into law on December 13, 2016, amended several sections of the Federal Food, Drug, and Cosmetic Act. This guidance was developed and issued prior to the enactment of Cures, and certain sections of this guidance may no longer be current as a result. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For more information please contact **CDRH-Cures@fda.hhs.gov (mailto:CDRH-Cures@fda.hhs.gov)**.

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 #P91-2

May 3, 1991

Panel Review of Premarket Approval Applications

Purpose

The Safe Medical Devices Act of 1990 (SMDA) has provided the Food and Drug Administration much needed discretion in the use of advisory panels in the review of premarket approval applications (PMAs). The purpose of this memorandum is to establish points to consider when deciding whether to take a PMA before an advisory panel for review and recommendation. This memorandum does not specifically address the situation in which an applicant disagrees with our decision to avoid panel review and requests that their PMA be referred to the appropriate panel for a formal review and recommendation.

Background

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act required that the agency refer all filed PMAs to the appropriate panel established under section 513 for study and submission of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. This requirement applied to all original PMAs, and many supplemental PMAs that were believed to pose issues that were analagous to those posed by their original counterparts (refer to PMA Memorandum #86-6 in the ODE Blue Book). The law did not overtly recognize the agency's ability to effectively evaluate data in any PMA or "panel-track" supplement independently without the assistance of a panel even when we had the necessary in-house scientific expertise or had developed the required expertise from panel deliberations on previously reviewed PMAs for similar devices.

Our interpretation of the legal requirements went so far as to cause us for years to take original PMAs that were nothing more than "licensing agreements"1 to panels for a report and recommendation on the approvability of the application. It was

not until April 18, 1986 that we developed a policy to eliminate redundant panel involvement in the approval of "licensing agreements."

On July 25, 1986, ODE developed a policy regarding panel review of PMAs for "me too" devices that was an attempt to meet the statutory requirements for panel review and to expedite PMA processing (refer to PMA Memorandum #86-6 in the ODE Blue Book). Under this directive, we could identify PMAs for "me too" devices and develop evaluation criteria that we could employ in evaluating the device's safety and effectiveness. So long as the appropriate panel had endorsed our evaluation criteria, we could independently apply the criteria to evaluate a PMA without direct panel involvement. Developing these detailed criteria proved to be a long and arduous task and too resource intensive to be a successful part of the PMA program.

Discussion

Our advisory panels undoubtedly provide much needed expertise in the review of the safety and effectiveness of all new medical devices. Clearly, the agency does not have the ability to hire and maintain the wide breadth of medical expertise needed to meet the challenge of evaluating the rapidly evolving new and innovative medical technology. Consequently, it is essential that we maintain an array of competent advisory panels to ensure our ability to accomplish our public health mission.

The maintenance and use of advisory panels is not, however, without expense. The cost of convening panel meetings is very high when one considers the time and effort expended by various agency personnel in preparing for a meeting and the travel and per diem costs in bringing experts from around the country to Washington, D.C. Additionally, panel members being recognized experts in the fields often must make personal and professional sacrifices to attend panel meetings when they are held.

1. Licensing agreements permit a PMA aplicant to obtain approval based upon specific agreements with the holder of an approved PMA. Uner such agreements, the basis for the orginal approval applied to the "licensing" PMA applicant.

SMDA provides the agency the much needed discretion on when to use advisory panels in the review of PMAs. The new legislation provides us the ability to consider factors such as (1) the expense of convening a meeting, (2) the legitimate scientific needs to properly evaluate a new medical device and (3) the agency's ability to meet the needs with in-house expertise when deciding whether panel input should be obtained. This new "discretion" that we have been afforded requires that we develop criteria to:

1. ensure internal consistency in decision-making;

2. clarify our review process to applicants;

3. ensure that advisory panels are used when they are needed to contribute to sound decision-making;

4. avoid the wasting of panel resources that result from convening panel meetings when they are unnecessary; and

5. expedite the review process by enabling reviewers to quickly decide if panel involvement is needed.

In order to address the above issues, criteria must be developed that will ensure we are justified in convening a panel to review a newly submitted PMA. It is important to note, however, that review divisions must evaluate the circumstances specific to each PMA and exercise great judgment in determining whether a panel review is warranted. It is impossible to establish criteria that will address all of the situations that we encounter in PMA review.

Criteria for Panel Involvement

When making the decision to take a PMA before an advisory committee, the review division should conclude that

1. we do not have the knowledge or experience to properly evaluate the types of safety and effectiveness questions posed by the new device without panel input;

2. the specific PMA raises a new issue that is best addressed by employing the breadth of knowledge and experience afforded by convening an advisory panel meeting; or

3. the data establishing the clinical performance of the device reveals unanticipated safety and effectiveness questions that would best be addressed through panel deliberations.

Guidance

Divisions are to take all measures required to eliminate unnecessary panel involvement in the evaluation of PMAs. Before scheduling a PMA for panel review, divisions are to consult the above criteria. In general, all PMAs for the first-of-a-kind device should be taken before the appropriate advisory panel for review and recommendation. As soon as division management believes that (1) the pertinent issues in determining the safety and effectiveness for the type of medical device are understood and (2) they have developed the ability to address those issues, future PMAs for devices of that type should not be taken before an advisory panel unless a particular application presents an issue that can best be addressed through panel review. Each division's management must ensure that the decision to involve, or not involve, a panel in the review of each PMA is well documented.

Furthermore, I expect each division's management to be prepared to justify panel involvement on all PMAs other than the first three PMAs for a new type of device. Should an applicant exercise their rights under SMDA and request that FDA refer their PMA to an appropriate panel for a formal review and recommendation, the review division is to consider the merits of such a request on a case-by-case basis.

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)