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.

Guidance for Industry and FDA Staff

Guidance on Amended Procedures for Advisory Panel Meetings

Document issued on: July 22, 2000

This document supersedes the document entitled "Guidance on Amended Procedures for Advisory Panel Meetings" dated 1/26/99.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Device Evaluation
Office of the Director

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Nancy J. Pluhowski, Office of Device Evaluation, HFZ-400, 9200 Corporate Boulevard, Rockville, MD 20850, or William Freas, Center for Biologics Evaluation and Research (HFM-21) 1401 Rockville Pike, Rockville, MD 20852. 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 Nancy J. Pluhowski (CDRH) at (301) 594-2022, or William Freas (CBER) at (301) 827-1295.

Additional Copies

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/modact/amendpan.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 413 when prompted for the document shelf number.

Guidance on Amended Procedures for Advisory Panel Meetings[1]

Purpose

The purpose of this guidance is to establish standard operating procedures to be followed by the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) personnel and interested persons outside FDA, in carrying out Section 513 (b)(6) of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by Section 208 of the FDA Modernization Act of 1997 (FDAMA). The standard operating procedures outlined below apply to advisory panel meetings where a specific submission is being considered by the panel.

Background on the New Provision

As stipulated in the new Section 513 (b)(6)(A)(i) of the Act, FDA is required to provide, to any person whose device is specifically the subject of a classification panel review, the same access to data and information about the device as that submitted to a classification panel, except for data and information that are not available for public disclosure under {5 U.S.C. 552}.

In accordance with Section 513 (b)(6)(A)(ii), FDA is required to provide to such persons the opportunity to submit information, based on the data or information provided in the application under review, to the panel for its review.

Section 513 (b)(6)(A)(iii) amended the Act to also allow such persons the same opportunity as FDA to participate in meetings of the panel.

Section 513 (b)(6)(B) of the Act requires of device classification panel meetings that: (1) adequate time be provided for initial presentations; (2) adequate time be provided for response to any differing views by persons whose devices are the subject of a classification panel; and (3) free and open participation by all interested persons be encouraged.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. 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.

Standard Operating Procedures

I. Premeeting Mailouts

A. At least 3 weeks before a device classification panel meeting to consider an action on a specific sponsor's device, FDA will provide to the panel members and the sponsor a prepared panel package (all pre-meeting materials that are sent to the entire panel, except for the industry representative who may receive a package that has been redacted at the sponsor's request) which contains:

1. appropriate sections of the product submission (i.e. preclinical and clinical data, summary of safety and effectiveness, labeling),
2. related information submitted by the sponsor,
3. FDA review memos (preclinical, clinical, statistical), or a summary of the FDA review memos,
4. FDA questions for panel consideration, and
5. outline or slides prepared for an FDA presentation (if available).

B. The following timeline and preparation of the panel package is recommended:

1. When available, but generally by six weeks before an advisory panel meeting, FDA will send to the sponsor an index of materials the Agency intends to include in the panel package. FDA will ask the sponsor to determine whether there is any additional information, directly related to the submission that the sponsor wants to include in the panel package.

2. The sponsor will therefore have approximately two weeks to submit additional information to be distributed to the panel. Such information should include a complete table of contents and an index. To be included in the initial panel package, the information should arrive at the Agency at least four weeks before the advisory panel meeting. The sponsor is asked to provide twenty copies of this information.

3. Upon receipt of the sponsor's materials for the panel package, FDA will assess the proposed panel package for completeness and relevance. FDA will determine if the added information is based on data or information in the PMA. Any question about the relatedness of the additional information will be discussed by telephone with the sponsor. This discussion will occur prior to the Agency's redacting material not based on data or information provided in the application.

4. FDA will send the complete panel package to the panel members and the sponsor simultaneously. Additional pertinent information, available to FDA after the initial panel package has been distributed, will be provided to the panel and sponsor as a panel package addendum. FDA will make every effort to mail the

addendum package, if there is one, one week before the advisory panel meeting.

5. In general, new data, analyses, or information from a sponsor, will not be provided to the panel within 2 weeks of the panel meeting, or at the meeting itself, unless it is responsive to questions [on the existing, evaluated set of data] identified by FDA or the panel. The additional information should not be of a type that could trigger a major amendment to the PMA. Additional information of this type may lead to the postponement of the advisory panel meeting to a later date.

II. FDA will provide the sponsor an equal amount of time to address the advisory panel as described below:

A. In order to provide adequate time for panel deliberations and at the discretion of the Chair:

1. The sponsor will generally be provided 60 minutes (up to 90 minutes if the sponsor requests and the Chair agrees they need additional time due to special circumstances) to present a submission to the advisory panel.

2. FDA's presentation will usually be limited to 60 minutes (similarly up to 90 minutes due to special circumstances) and will include specific issues identified during the review process, unresolved issues, and deficiencies in the submission.

3. Following initial presentations, the sponsor and FDA, respectively, will each be provided equal opportunities (up to 15 minutes) to clarify issues or information presented during the panel meeting.

4. The panel may require clarification during the panel's deliberations and before a vote is taken on the submission. In such cases, both FDA and the sponsor will be provided an equal opportunity to respond.

B. Encourage free and open participation by all interested persons:

1. The open public session of the advisory committee meeting provides a time for free and open participation by all interested persons.

2. Generally, the open public session lasts one hour and will be conducted in two segments: approximately 30 minutes at the beginning of the panel meeting for general or specific issues and 30 minutes near the end of the panel deliberations, prior to the vote, for interested persons to address issues specific to the submission before the panel.

These standard operating procedures also will be applied to device classification panel meetings on issues involving more than one sponsor. In such cases, however, the time available per sponsor may be more limited than indicated above. Further discussion of these procedures will be in the revised Policy and Guidance Handbook for FDA's Advisory Committees.