DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0172]

Guidance on Amended Procedures for Advisory Panel Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings.'' The purpose of the guidance document is to establish standard operating procedures (SOP's) to be followed by the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), FDA personnel, and interested persons outside FDA in carrying out the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments concerning the guidance document may be submitted at any time.

ADDRESSES: Submit written comments on the guidance document to one of the contact persons listed below. Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022; or William Freas, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–1295.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings'' was developed to establish SOP's to be followed by CDRH, CBER, FDA personnel, and interested persons outside FDA in carrying out section 513(b)(6) of the act (21 U.S.C. 360c(b)(6)) as amended by section 208 of FDAMA. New section 513(b)(6)(A) of the act requires that FDA provide to any person whose device is specifically the subject of a classification panel review the same access as FDA to data and information about the device as that submitted to the panel, except for data and information that are not available for public disclosure under the Freedom of Information Act (5 U.S.C. 552). FDAMA further amended the act to require FDA to provide 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)(iii) amended the act to allow such persons the same opportunity as FDA to participate in panel meetings. Section 513(b)(6)(B) of the act requires that adequate time be provided for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel, and that free and open participation by all interested parties be encouraged. FDA announced the availability of the draft guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings'' in the **Federal Register** of March 31, 1998 (63 FR 15426). The agency received one comment on the draft guidance document. FDA has reviewed the comment and has made some revisions to clarify the guidance. In addition, FDA agrees with the comment that another guidance document entitled ''Policy and Guidance Handbook for FDA's Advisory Committees'' should be subject to the agency's good guidance practices (GGP's). That guidance document is currently being revised.

This revised guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings'' supersedes the guidance document that was announced on March 31, 1998.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the amended procedures for advisory panel meetings. 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.

The agency has adopted GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 413 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance on Amended Procedures for Advisory Panel Meetings,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The guidance document entitled ''Guidance on Amended Procedures for Advisory Panel Meetings'' will be available on CDRH's website at http://www.fda.gov/cdrh/modern/modguid.html and on CBER's website at http://www.fda.gov/cber/guidelines.htm.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance document to one of the contact persons listed above. Such comments will be considered when determining whether to amend the current guidance.

Dated: January 10, 1999.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 99–1662 Filed 1–25–99; 8:45 am]

BILLING CODE 4160–01–F