10591–9005. The petition proposes to amend the food additive regulations to provide for the safe use of 2-hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives complying with § 175.105 *Adhesives* (21 CFR 175.105) and pressure-sensitive adhesives complying with § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 13, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–8302 Filed 3–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0172]

Amended Procedures for Advisory Panel Meetings; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Amended Procedures for Advisory Panel Meetings.'' The purpose of the guidance document 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), FDA personnel, and interested persons outside FDA in carrying out the Federal Food, Drug, and Cosmetic Act (the act), as amended through the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments concerning the draft guidance must be received by June 29, 1998. After the close of the comment period, written comments may be submitted at any time to the contact person listed below.

ADDRESSES: Written comments concerning the draft guidance that are submitted within the 90 days comment period must be addressed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in heading of this document. Submit written requests for singles copies of the draft guidance to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr.,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 electronic access to the guidance.

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.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance document entitled ''Amended Procedures for Advisory Panel Meetings'' was developed to establish standard operating procedures to be followed by the 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. Beginning on February 19, 1998, section 513(b)(6)(A) of the act requires that FDA provide to any person whose device is subject to a classification panel review be given the same access to data and information submitted to a classification panel except 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 any person whose device is under review by a classification panel to have the opportunity to submit information based on the data or information provided in the application to the panel for its review. It also provides the same opportunity as the Secretary of Health and Human Services 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 persons be encouraged.

II. Significance of Guidance

The 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 guidance document entitled ''Amended Procedures for Advisory Panel Meetings'' is a Level 1 guidance document under FDA's Good Guidance Practices Policy. Public comment prior to implementation of the guidance document is not required because the guidance is needed to implement new statutory requirements enacted by FDAMA.

III. Comments

Interested persons may, on or before June 29, 1998, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. After June 29, 1998, written comments may be submitted at any time to the contact person listed above.

IV. Electronic Access

In order to receive the draft guidance entitled ''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 prompt to complete your request.

Persons interested in obtaining a copy of the draft guidance 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 the guidance document entitled ''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 ''Amended Procedures for Advisory Panel Meetings'' will be available at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: March 25, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–8301 Filed 3–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0173]

PMA/510(k) Expedited Review Guidance for Industry and Center for Devices and Radiological Health Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''PMA/510(k) Expedited Review Guidance for Industry and the Center for Devices and Radiological Health (CDRH) Staff.'' FDA believes it is in the interest of the public health to review premarket approval applications (PMA's) and premarket notifications (510(k)'s) for certain medical devices in an expedited manner. The expedited review will generally be considered when a device offers a potential for clinically meaningful benefit as compared to the existing alternatives (preventive, diagnostic, or therapeutic) or when the new medical device promises to provide a revolutionary advance (not incremental advantage) over currently available alternative modalities.

DATES: Submit written comments concerning this guidance by June 29, 1998. After the close of the comment period, written comments may be submitted at any time to one of the contact persons listed in this document.

ADDRESSES: Written comments concerning this guidance that are submitted within the 90-day comment period must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance on a 3.5'' diskette 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.

FOR FURTHER INFORMATION CONTACT:

On expedited review for PMA's:
Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

For expedited review for 510(k)'s:
Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The criteria and procedures under which expedited review would apply to PMA's and Premarket Notifications (510(k)'s) for medical devices were previously identified in General Program Memorandum #G94–2, ''PMA/510(k) Expedited Review.'' In order to reflect the criteria in section 515(d)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(5)), as modified by section 202 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) entitled ''Special Review for Certain Devices,'' the criteria section of the guidance has been modified. These modifications include rearranging the first three criteria and revising the fourth to track the new statutory language more closely. All other sections of the guidance remain the same. This document rescinds and replaces General Program Memorandum #G94–2, ''PMA/510(k) Expedited Review.''

These procedures are based upon the Management Action Plan initiative paper entitled ''PMA/510(k) Expedited Review Process.'' This guidance embodies the procedures flowing from that issue paper and implements the principles in that document as the policy of the Office of Device Evaluation (ODE). This Blue Book Memorandum will be used by ODE reviewers in applying procedures for the review of incoming PMA's and 510(k)'s.

FDA believes it is in the interest of the public health to review PMA's and 510(k)'s for certain medical devices in an expedited manner. Expedited review will generally be considered when a device offers a potential for clinically meaningful benefit as compared to the existing alternatives (preventative, diagnostic, or therapeutic) or when the new medical device promises to provide a revolutionary advance (not incremental advantage) over currently available alternative modalities.

Granting of expedited review status means that the marketing application would receive priority review before other pending PMA's and 510(k)'s, i.e., the application will be placed at the beginning of the appropriate review queue. If multiple applications for the same type of medical device offering comparable advantage over existing approved alternatives have been granted expedited review, the applications will be reviewed with priority according to their respective submission due dates. Once one of the applications is approved, those of the same type still pending will generally lose their expedited review status with regard to review resources but will retain their place in the review queue.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the procedures to be followed for expedited review of PMA's and (510(k)'s). 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.

This guidance document entitled ''PMA/510(k) Expedited Review Guidance for Industry and CDRH Staff'' is a Level 1 guidance under FDA's Good