B. PMA Supplements

In accordance with FDA regulations, PMA supplements ordinarily are required to be reviewed within 180 days (21 CFR 814.39(c)).

The legislative history of section 403 of FDAMA indicates that Congress expected FDA to publish performance standards for those supplements submitted for changes in product use. Therefore, the data that follow do not reflect FDA performance standards for PMA supplements submitted for other changes, e.g., labeling or manufacturing. Historically, FDA has received approximately 300 to 500 PMA supplements per year. Approximately 10 percent of these supplements address changes in the indication for use. Performance for the PMA supplement receipt cohort for changes in indication received during fiscal year (FY) 1996 and FY 97 was just over 70 percent completed within 180 days.

Tracking for PMA supplements will continue to be accomplished using Receipt Cohorts as the basis for program performance. Projected performance for the FY 98 receipt cohort for changes in indication is expected to be 65 percent reviewed within 180 days. This estimate is based on making the best use of available FY 98 resources during a time of increasing workload attributable to implementation of FDAMA. In FY 99, FDA will continue reengineering the device review process with emphasis on these new requirements. If adequate funding is provided, FDA expects that performance will be back to 70 percent in FY 99 and anticipates enhanced performance levels in subsequent years.

III. FDAMA Section 403(c)

FDA has designated the following individuals within CDRH and CBER to work with sponsors to facilitate the development and submission of data to support supplemental applications for approved articles in accordance with section 403(c) of FDAMA:

Director, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022, and

Deputy Director, Medical Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028.

IV. Comments

Interested persons may, on or before August 19, 1998, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 18, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13721 Filed 5–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0333]

Guidance for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled, ''Guidance for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review.'' The FDA Modernization Act of 1997 (FDAMA) requires the agency to issue final guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application, specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application and define supplemental applications that are eligible for priority review.

DATES: Written comments concerning this guidance may be submitted at anytime.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled, ''Guidance for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, 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.

Submit written comments on ''Guidance for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review'' to the contact persons listed below. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186; or

Jerome A. Donlon, Center for Biologics Evaluation and Research, 1401 Rockville Pike (HFM–200), Rockville, MD 20852–1448, 301–827–3028.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(b) of FDAMA (Pub. L.105–115) provides that not later than 180 days after the date of enactment, the Secretary of the Department of Health and Human Services (FDA by delegation) shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for approved articles under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262). The guidances shall:

(1) Clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) Specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) Define supplemental applications that are eligible for priority review.

Section 403(b) of FDAMA is applicable to multiple centers within FDA. Availability of the draft guidance prepared by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) (CDER/CBER draft guidance) was announced in the **Federal Register** of March 21, 1997 (62 FR 13650). The CDER/CBER draft guidance describes the use of literature and the types of study design that may support supplemental effectiveness claims for approved drug and biological products. CDRH issued draft guidance

on March 20, 1998, that set forth its perspective on the applicability of the CDER/CBER draft guidance to medical devices.

The agency received two comments on the draft guidance. Both comments encouraged the agency to issue two separate guidance documents, one for devices and one for drugs and biologics, rather than a single guidance document. Also, both comments requested device-specific examples in the guidance document. One comment requested additional guidance on other provisions of FDAMA.

Although CDRH initially had expected the final guidance issued in accordance with 403(b) of the act to be a single agency document that addressed devices, drugs and biologics, both CDRH and CBER have decided, in the interest of clarity and consistent with comments received on the draft guidance, to issue a separate guidance document for medical devices. This final guidance for medical devices builds upon the foundation developed in the CDER/CBER draft guidance regarding the use of published literature, draws upon the existing premarket approval application (PMA) regulation, and refers to earlier guidance documents developed by CDRH that describe efforts to avoid duplication of previously submitted data and that define supplemental applications that are eligible for priority review. In this final guidance, device specific examples have replaced the drug examples presented in the CDER/CBER draft guidance.

This guidance has been revised to account for all class III products approved as PMA's, including humanitarian device exemption (HDE) products and product development protocols (PDP's). A Class III device for which a PDP has been declared completed by FDA is considered to have an approved PMA § 814.19 (21 CFR 814.19). Supplements to PDPs, therefore, will be treated as PMA supplements for purposes of this guidance. This guidance also provides examples of how the use of published literature may be used in support of a PMA, PDP, or HDE supplement.

Published literature would most frequently be used to support supplements for new indications for use of an approved device. In accordance with § 814.110, an applicant seeking approval for a new indication for use for an approved humanitarian use device must submit an original HDE. Therefore, this guidance would apply to HDE supplements only in unusual circumstances. The agency intends to issue additional guidance documents on other provisions of FDAMA and will solicit public comment on those guidances in accordance with FDA's Good Guidance Practices.

II. Significance of Guidance

This guidance document represents the agency's current thinking on ''Guidance for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review.'' Both the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) have responsibilities for the regulation of medical devices. This document applies to medical devices regulated by either CDRH or CBER and reflects the current thinking of both centers on the subject of this guidance. This document does not apply to medical devices licensed by CBER. This document is being issued as final guidance. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (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 GGPs. Written comments may be submitted at any time.

III. Electronic Access

In order to receive ''Guidance for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review'' via your fax machine, call the CDRH Facts-On-Demand (FOD) 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 (380) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web 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 for Industry, Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review,'' 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. This guidance is also available from CBER on the World Wide Web at http://www.fda.gov/cber/guidelines.htm.

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.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this final guidance. Such comments will be considered when determining whether to amend the current guidance. 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 18, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13720 Filed 5–20–98; 8:45 am]

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