January 26, 1993, the R. W. Johnson Pharmaceutical Research Institute notified FDA in writing that carbinoxamine maleate (Clistin®) 4-mg immediate-release tablets were no longer being marketed under NDA 8–915 and requested the withdrawal of that application. FDA complied and announced the withdrawal of approval for NDA 8–915 in the **Federal Register** of March 2, 1994 (59 FR 9989).

FDA has reviewed its records and, under § 314.161, has determined that carbinoxamine maleate 4-mg immediate-release tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain carbinoxamine maleate 4-mg immediate-release tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to carbinoxamine maleate 4-mg immediate-release tablets may be approved by the agency.

Dated: May 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13468 Filed 5–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0317]

Prompt Review of Supplemental Applications for Approved Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), in accordance with the FDA Modernization Act of 1997 (FDAMA), are publishing standards for the prompt review of supplemental applications submitted for devices approved under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*). Also, in accordance with FDAMA, CDRH and CBER are designating an individual within each center to be responsible for encouraging prompt review of supplements and for working with sponsors to facilitate development and submission of data to support such supplements.

DATES: Written comments by August 19, 1998.

ADDRESSES: Submit written comments concerning this notice 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.

FOR FURTHER INFORMATION CONTACT:

Robert M. Navazio, Center for Devices and Radiological Health (HFZ–30), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1282, or

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

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA was enacted on November 21, 1997, in order to streamline the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Section 403 of FDAMA addresses FDA's review of supplemental applications (''supplements'') submitted for articles approved under the act or section 351 of the Public Health Service Act.

Section 403(a) of FDAMA requires FDA to publish in the **Federal Register**, not later than 180 days after enactment of FDAMA, standards for the prompt review of supplements. Section 403(b) requires FDA to issue final guidances by that same date to clarify the requirements for, and facilitate the submission of, data to support the approval of supplements. Section 403(b) also requires the guidance to clarify those circumstances in which published matter may be the basis for approval of supplements, to specify data requirements that will avoid duplication of previously submitted data, and to define those supplements that are eligible for priority review. Section 403(c) requires FDA to designate an individual within each center of FDA (except the Center for Food Safety and Applied Nutrition) to be responsible for encouraging prompt review of supplements and working with sponsors to facilitate development and submission of data to support supplements. Section 403(d) requires FDA to implement programs and policies that will foster collaboration between FDA, the National Institutes for Health, and others to identify studies that may support supplements and to encourage sponsors to submit and develop supplements based on such studies.

In this notice, CDRH and CBER are publishing performance standards they have established for the prompt review of premarket approval application (PMA) supplements, in accordance with section 403(a) of FDAMA. Also, the Director, Office of Device Evaluation, CDRH, and the Deputy Director, Medical, CBER are designated as the individuals within each center who will be responsible for encouraging the prompt review of PMA supplements and working with sponsors to facilitate development and submission of data to support supplements, in accordance with section 403(c). Elsewhere in this issue of the **Federal Register**, CDRH is publishing a notice of availability of final guidance to industry to clarify the requirements for, and facilitate the submission of, data to support the approval of supplements, in accordance with section 403(b).

II. FDAMA Section 403(a)

Following approval of a PMA or receipt of an order declaring a product development protocol (PDP) completed, the sponsor of the approved PMA or completed PDP must submit a supplement to the PMA or PDP for review and approval by FDA before making a change affecting the safety and effectiveness of the device, unless the device is of a type for which FDA has advised that an alternate submission is permitted.

FDA measures its performance with respect to review of supplements by tracking and analysis of groups of incoming applications. These groups of submissions are referred to as Receipt Cohorts.

A. PDP Supplements

In accordance with 21 CFR 814.19, a class III device for which a product development protocol has been declared completed by FDA will be considered to have an approved PMA. Accordingly, FDA intends to review PDP supplements in the same timeframe it reviews PMA supplements.

FDA does not have baseline data for PDP supplements because no submissions of such supplements have been received. To the extent applicable, FDA intends to apply to PDP supplements the same performance standards described below for PMA supplements.

FR 34514), FDA withdrew approval of NDA 8–915 as it pertained to Clistine® R–A because no person submitted bioavailability data showing that the product was effective as a controlled-release dosage form.

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]

BILLING CODE 4160–01–F

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