## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### CDC Advisory Committee on HIV and STD Prevention; Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

*Name:* CDC Advisory Committee on HIV and STD Prevention.

*Times and Dates:*

8:30 a.m.–5 p.m., June 16, 1998.

8:30 a.m.–12 p.m., June 17, 1998.

*Place:* Corporate Square Office Park, Corporate Square Boulevard, Building 11, Room 1413, Atlanta, Georgia 30329.

*Status:* Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

*Purpose:* This Committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

*Matters to be Discussed:* Agenda items include issues pertaining to syphilis elimination; HIV prevention activities in the rural U.S.; and priority prevention services for HIV-infected persons. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Beth Wolfe, Committee Management Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, Mailstop E–07, Atlanta, Georgia 30333, telephone (404) 639–8008.

Dated: May 15, 1998.

**Nancy C. Hirsch,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 98–13550 Filed 5–20–98; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Mine Health Research Advisory Committee Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

*Name:* Mine Health Research Advisory Committee (MHRAC).

*Time and Date:* 9 a.m.–4 p.m., June 26, 1998.

*Place:* The Washington Court Hotel, Montpelier Room, 525 New Jersey Avenue, NW., Washington, DC 20001.

*Status:* Open to the public, limited only by space available. The meeting room accommodates approximately 50 people.

*Purpose:* The Committee is charged with advising the Secretary; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; and the Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), ection 102(b)(2).

*Matters to be Discussed:* The agenda will include MHRAC history; funding; the Federal Advisory Committee Act; Research Program Transition: FY 1996–FY 1998; FY 1997 and FY 1998 Accomplishments in Disaster Prevention and Response; and Mining Research Gaps and Emerging Themes.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Larry Grayson, Ph.D., Executive Secretary, MHRAC, NIOSH, CDC, 200 Independence Avenue, SW., Room 715–H, Humphrey Building, Washington, DC 20201, telephone (202) 401–2192, fax (202) 260–4464.

Dated: May 15, 1998.

**Nancy C. Hirsch,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 98–13549 Filed 5–20–98; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98P–0062]**

### Determination That Carbinoxamine Maleate 4–Milligram Immediate-Release Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that carbinoxamine maleate (Clistin®) 4-milligram (mg) immediate-release tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for carbinoxamine maleate 4-mg immediate-release tablets.

**FOR FURTHER INFORMATION CONTACT:** Richard L. Schwartzbard, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated January 22, 1998 (Docket No. 98P–0062/CP1), submitted in accordance with 21 CFR 314.122, Sage Pharmaceuticals requested that the agency determine whether carbinoxamine maleate (Clistin®) 4-mg immediate-release tablets were withdrawn from sale for reasons of safety or effectiveness. Carbinoxamine maleate (Clistin®) 4-mg immediate-release tablets were the subject of approved NDA 8–915.[1] On

[1] NDA 8–915 also covered Clistin® R–A, a controlled-release form of carbinoxamine maleate tablets. In the **Federal Register** of July 29, 1983 (48

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.