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]

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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]

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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