

STD Prevalence, Tuberculosis, and HIV Risk Behaviors among Men Who have Sex with Men, Program Announcement # 99000-E.

Time and Date: 8:30 a.m.-9 a.m., September 1, 1999 (Open); 9 a.m.-4:30 p.m., September 1, 1999 (Closed).

Place: National Center for HIV, STD, and TB Prevention, CDC, Corporate Square, Building 12, Conference Room 1306, Atlanta, Ga. 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement # 99000-E. Due to administrative delays this notice is published less than 15 days prior to the meeting.

Contact person for more information: Beth Wolfe, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 11 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639-8025, e-mail eow1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 16, 1999.

Carolyn J. Russell,

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

[FR Doc. 99-21770 Filed 8-18-99; 12:52 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreements for an Evaluation Research Study in the Area of Aggression and Interpersonal Youth Violence

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 meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreements for an Evaluation Research Study in the Area of

Aggression and Interpersonal Youth Violence, Program Announcement # 99067.

Time and Date: 8 a.m.-8:30 a.m., August 31, 1999 (Open); 8:30 a.m.-5 p.m., August 31, 1999 (Closed).

Place: Atlanta Airport Hilton and Towers, Grand Salons A, B, and C, 1031 Virginia Avenue, Hapeville, GA 30354.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement # 99067. Due to administrative delays this notice is published less than 15 days prior to the meeting.

Contact Person for More Information: James Belloni, Office of the Director, National Center for Injury Prevention and Control, 4770 Buford Highway, NE, M/S K02, Atlanta, Georgia 30341-3724, telephone 770/488-4538, e-mail jsb1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 17, 1999.

Carolyn J. Russell,

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

[FR Doc. 99-21771 Filed 8-18-99; 12:52 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreement for a Coordinated Community Response to Prevent Intimate Partner Violence

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 meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreement for a Coordinated Community Response to Prevent Intimate Partner Violence, Program Announcement # 99133.

Times and Dates: 8:30 a.m.-9 a.m., August 26, 1999 (Open); 9 a.m.-5 p.m., August 26, 1999 (Closed); 8:30 a.m.-5 p.m., August 27, 1999 (Closed).

Place: National Center for Injury Prevention and Control, Conference Room 2052, 2945 Flowers Road South, Atlanta, Ga. 30341.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement # 99133. Due to administrative delays this notice is published less than 15 days prior to the meeting.

Contact Person for More Information: James Belloni, Office of the Director, National Center for Injury Prevention and Control, 4770 Buford Highway, NE, M/S K02, Atlanta, Georgia 30341-3724, telephone 770/488-4538, e-mail jsb1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 17, 1999.

Carolyn J. Russell,

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

[FR Doc. 99-21772 Filed 8-18-99; 12:52 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project Title: Online Interstate Referral Guide (IRG).

OMB No.: New.

Description: The IRG is an essential reference maintained by the federal Office of Child Support Enforcement (OCSE) that provides State IV-D agencies with the information needed to process interstate cases. The online version of the IRG will provide States with an effective and efficient way of viewing and updating State profile, address, and FIPS code information by consolidating data available through numerous discrete sources into a single centralized, automated repository.

Respondents: Federal, State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Online IRG	54	18	.3	292

Estimated Total Annual Burden Hours: 292.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 17, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99-21747 Filed 8-20-99; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2532]

Determination That Astemizole 10-Milligram Tablets Were Withdrawn From Sale for Safety Reasons

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that astemizole 10-milligram (mg) tablets (Hismanal) were withdrawn from sale for safety reasons. The agency will not accept or approve abbreviated new drug applications (ANDA's) for astemizole 10-mg tablets.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of approved innovator drug products under an ANDA procedure. ANDA sponsors generally must 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 drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's are not required to repeat the extensive clinical testing necessary to gain approval of an NDA. The only data from investigations 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 include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), 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 (§ 314.162 (21 CFR 314.162)). FDA may not approve an ANDA that does not refer to a listed drug (21 CFR 314.92(a)).

Astemizole 10-mg tablets (Hismanal) are the subject of approved NDA 19-402, currently held by Janssen

Pharmaceutica (Janssen). In 1988, FDA approved the NDA for Hismanal tablets for the relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria. On June 18, 1999, Janssen withdrew Hismanal tablets from sale in the United States. The agency's review of the withdrawal of astemizole 10-mg tablets (Hismanal) from the market has considered the sponsor's explanation of the basis for the withdrawal of the product and information available to the agency regarding Hismanal. The current evidence supports the conclusion under § 314.161 (21 CFR 314.161) that astemizole 10-mg tablets (Hismanal) were withdrawn from the market for safety reasons.

The agency has determined, under § 314.161, that astemizole 10-mg tablets (Hismanal) were withdrawn from the market for safety reasons. Accordingly, the agency will remove astemizole 10-mg tablets (Hismanal) from the "Orange Book" (§ 314.162). FDA will not accept or approve ANDA's that refer to this drug product.

Dated: August 13, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-21813 Filed 8-20-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2670]

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.