DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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.

Date and Time: The meeting will be held on March 11, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *patela@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications 21–797 and 21–798, entecavir tablets and entecavir oral solution, respectively, Bristol-Myers Squibb Co., proposed for the treatment of patients with chronic hepatitis B infection (HBV).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Angie Whitacre at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 23, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Access to Recovery (ATR) Program—New

In preparation for implementing Performance Partnership Grants, SAMHSA has developed a set of performance outcome measures for substance abuse treatment that cover seven domains. The domains are: Abstinence from drug use and alcohol abuse, or decreased mental illness symptomatology; increased or retained employment and school enrollment; decreased involvement with the criminal justice system; increased stability in family and living conditions; increased access to services; increased retention in services for substance abuse treatment or decreased utilization of psychiatric inpatient beds for mental health treatment; and increased social connectedness to family, friends, co-workers and classmates.

SAMHSA's Center for Substance Abuse Treatment (CSAT), is responsible for implementing the new Access to Recovery (ATR) grant program. States funded in the ATR program will use these outcome measures to meet the reporting requirements of the Government Performance and Results Act (GPRA) by quantifying the effects and accomplishments of the funded programs. The ATR Program is part of a Presidential initiative to: (1) Provide client choice among substance abuse clinical treatment and recovery support service providers, (2) expand access to a comprehensive array of clinical treatment and recovery support options (including faith-based programmatic options), and (3) increase substance abuse treatment capacity. Monitoring outcomes, tracking costs, and preventing waste, fraud and abuse to ensure accountability and effectiveness in the use of Federal funds are also important elements of the ATR program. Grantees, as a contingency of their award, are responsible for collecting data from their clients at intake, discharge, at 30 days after intake, and every two months during an episode of care. An episode of care is defined as a client's entry to and exit from the ATR.

The following tables summarize the annual response burden for the ATR activities using the performance outcome measures.

Data collection point	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden (proportion of added burden)*
Client Interviews:					
ATR Intake	42,095	1	42,095	0.33	7,640
Discharge/30 day interview**	42,095	1	42,095	0.33	13,891
3 months	28,625	1	28,625	0.33	9,446
5 months	22,732	1	22,732	0.33	7,502
7 months	18,101	1	18,101	0.33	5,973
9 months	15,155	1	15,155	0.33	5,001