

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 Dearyburk Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05-1578 Filed 1-27-05; 8:45 am]

BILLING CODE 4160-01-S

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 |

| Data collection point | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hour burden (proportion of added burden)* |
|---|-----------------------|--------------------------|-----------------|--------------------|---|
| 11 months | 11,787 | 1 | 11,787 | 0.33 | 3,890 |
| 12 months*** | 7,999 | 1 | 7,999 | 0.33 | 2,640 |
| Total | 188,589 | | 188,589 | | 55,983 |
| Record Management by Provider Staff: Sections A and G per client at each data collection point after intake | 146,494 | 1 | 146,494 | .16 | 23,439 |
| Voucher information and transaction | 42,095 | 1.5 | 63,143 | .03 | 1,894 |
| Provider staff total per client | 188,589 | | 209,637 | | 25,333 |
| Grantees (14 States and 1 Tribal Organization): Grantee extract and upload | 15 | 4 | 60 | .03 | 2 |
| Total | 377,193 | | 398,226 | | 81,318 |

* This estimate is an added burden proportion which is an adjustment reflecting the extent to which programs typically already collect the data items. The formula for calculating the proportion of added burden is: total number of items in the standard instrument, minus the number of core items currently included, divided by the total number of items in the standard instrument. Thus, 13,891 times .55 proportion of added burden = 7,640. This only applies to the intake interview.

** The ATR interview will be administered every 2 months beginning at 30 days. It is assumed that those who are discharged at 30 days or less will receive an intake and discharge interview only and are included in the number in the first two rows. The number of respondents who are still in treatment by month is based on experience with CSAT's GPRA services data.

*** Based on experience with CSAT's GPRA services data, it is expected that few clients will still be in treatment longer than 12 months.

1\1 Clients.

Written comments and recommendations concerning the proposed information collection should be sent by February 28, 2005 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395-6974.

Dated: January 24, 2005.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 05-1583 Filed 1-27-05; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

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

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management

and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Title: Emergency Management Institute Follow-up Evaluation Survey.

OMB Number: 1660-0044.

Abstract: FEMA Form 95-56 is a continuous self-assessment qualitative tool used to identify trainees' knowledge and skills gained through emergency management-related courses and the extent to which they have been beneficial and applicable in the conduct of their official positions. The information collected is primarily used to review course content and offerings for program planning and management purposes. Results are combined with other program metrics to document performance per GPRA mandates.

Affected Public: Individuals or households; State, local or tribal governments.

Number of Respondents: 2,300.

Estimated Time Per Respondent:

FEMA Form 95-56, 15 minutes; Students participating in pilot testing for electronic version of FEMA Form 95-56, 30 minutes.

Estimated Total Annual Burden Hours: 600.

Frequency of Response: One per course.

COMMENTS: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Department of Homeland Security/FEMA, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, or facsimile number (202) 395-7285. Comments must be submitted on or before February 28, 2005.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection should be made to Muriel B. Anderson, Section Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646-3347, or e-mail address FEMA-Information-Collections@dhs.gov.

Dated: January 21, 2005.

Edward W. Kernan,

Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05-1571 Filed 1-27-05; 8:45 am]

BILLING CODE 9110-17-P