Dated: October 14, 2005.

Karen V. Gregory,

Assistant Secretary.

[FR Doc. 05–20913 Filed 10–18–05; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for ''The Centers for Education and Research on Therapeutics (CERTs),'' are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: The Centers for Education and Research on Therapeutics (CERTs).

Date: November 2–3, 2005 (Open on November 2 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

Place: John M. Eisenberg Building, AHRQ Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427-1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: October 07, 2005.

Carolyn M. Clancy,

Director.

[FR Doc. 05–20937 Filed 10–18–05; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0367]

Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), investigational new drug applications (INDs), master files, advertising material, and promotional labeling using the electronic common technical document (eCTD) specifications. The submission of these documents in electronic format should improve the agency's efficiency in processing, archiving, and reviewing them.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, e-mail: *levinr@cder.fda.gov,* or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.'' This document provides guidance to industry regarding submission of marketing applications (NDAs, ANDAs, BLAs), INDs, and related submissions (master files, advertising, and promotional labeling) in electronic format based on the International Conference on Harmonisation eCTD specifications.

In the **Federal Register** of August 29, 2003 (68 FR 52044), FDA made available a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions'' and gave interested persons an opportunity to submit comments by October 28, 2003. The agency considered received comments as it finalized this guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing applications and related submissions in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control number 0910–0014 (until January 31, 2006), OMB control number 0910–0001 (until May 31, 2008), and OMB control number 0910–0338 (until September 30, 2008).

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20921 Filed 10–18–05; 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: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

Proposed Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930–0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101–645, 42 U.S.C. 290cc–21 et seq., the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 et seq. of the Public Health Service (PHS) Act). Section 522 of the PHS Act requires that the grantee States and Territories must expend their payments under the Act solely for making grants to political subdivisions of the State, and to non-profit private entities (including community-based veterans organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act specifies that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The estimated annual burden for these reporting requirements is summarized in the table below.

Respondents	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
States	56	1	26	1,456
Local provider agencies	450	1	31	13,950
Totals	506	.....	.....	15,406

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 71–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 11, 2005.

Anna Marsh,

Director, Office of Program Services.

[FR Doc. 05–20884 Filed 10–18–05; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–22721]

Lower Mississippi River Waterway Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Lower Mississippi River Waterway Safety Advisory Committee (LMRWSAC) will meet to discuss various issues relating to navigational safety on the Lower Mississippi River and related waterways. The meeting will be open to the public.

DATES: The next meeting of LMRWSAC will be held on Tuesday, November 15, 2005, from 9 a.m. to 12 p.m. This meeting may adjourn early if all business is finished. Requests to make