

heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the workshop will remain open until October 31, 1995. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (address above) by October 31, 1995.

Dated: July 28, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-19087 Filed 8-2-95; 8:45 am]

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### Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETING:** The following advisory committee meeting is announced:

#### Joint Subcommittee Meeting of the National Task Force on AIDS Drug Development and the Antiviral Drugs Advisory Committee on Clinical Trial Design Issues

*Date, time, and place.* September 8, 1995, 8:30 a.m., Auditorium, William H.

Natcher Conference Center, National Institutes of Health, 45 Center Dr., 2BC.02, Bethesda, MD.

*Type of meeting and contact person.* Open committee discussion, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 4 p.m.; Heidi C. Marchand or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF-12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0104, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602, or Antiviral Drugs Advisory Committee, code 12531.

*General functions of the committees.* The National Task Force on AIDS Drug Development shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers, and provides options for the elimination of these barriers. The Antiviral Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Those desiring to make formal presentations should notify a contact person before August 25, 1995, 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 required to make their comments.

*Open subcommittee discussion.* The subcommittee will hear summary presentations from discussions held during the public workshop on current issues in AIDS clinical trials to be held on September 6 and 7, 1995, (announced elsewhere in this issue of the **Federal Register**) and discuss recommendations on the scientific design of AIDS clinical trials.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of

data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page.

The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: July 18, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*

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**Health Resources and Services Administration**

**Proposed Data Collections Available for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the

Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited 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) 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 Projects**

1. Reporting Requirements for Ryan White CARE Act of 1990, Title IV—The Maternal and Child Health Bureau (MCHB) proposes to collect aggregated data from 38 grantees and their local

service providers that are funded under Section 2671 of the Public Health Service Act (42 USC 300ff-71) about the organizational structures, service delivery approaches, numbers and demographic characteristics of clients served, service utilization, and activities related to outreach, prevention, and education. The Data Collection Strategy includes six tables that the 38 grantees and their local service providers will use to submit information annually about program and client characteristics. The purpose is to document the efforts of grantees to develop comprehensive systems of care for infants, children and families and to provide these patients with access to research. The data collected will be used within and outside MCHB and HRSA to inform the administration and Congress about the Title IV program and will be used by grantees and MCHB for other planning, research, and policy efforts. Burden estimates are as follows:

Type of form	Number of respondents	Responses per respondent	Range* (hours)	Average burden per response (hours)
Designation of Local Reporting Entities .....	38	1	.1-1.0	.5
Local Network Profile .....	38	1	.1-2.5	1.0
Service Mix Profile .....	85	1	1-44	2.5
Demographic and Clinical Status .....	85	1	4-120	33.0
Service Utilization Summary .....	85	1	1-70	20.0
Prevention and Education Activities .....	85	1	1-44	4.0

\* Estimates are based on phone conversations with 6 grantees.

2. Health Professions Student Loan Program and Nursing Student Loan Program Debt Management Report—Extension—The Debt Management Report is used by three programs (Health Professions Student Loan (HPSL) Program, Nursing Student Loan (NSL) Program, and Loans for Disadvantaged Students (LDS) Program) to monitor the fiscal activities of participating schools. Data are requested on collection activities, investment income, return of excess cash, compliance with performance standards, and the return of the Federal share of monies collected. The report is submitted electronically once a year. No substantive changes in the data elements are proposed. Burden estimates are as follows:

Type of form	Number of respondents	Responses per respondent	Average burden per response
6-month report.	1,503	1	1 hour.

3. Health Education Assistance Loan (HEAL) Program Physician's Certification of Borrower's Total and Permanent Disability Form—New—This form, completed by the HEAL borrower, the borrower's physician, and the holder of the loan, is used to certify that the HEAL borrower meets the total and permanent disability provisions. The PHS will use this form to obtain precise information about the disability claim which includes the following: 1) the borrower's consent to release medical

records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, 2) pertinent information supplied by the certifying physician, 3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and 4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in a disability claim not being honored.