Health Study Section to consider safety and occupational health related grant applications. These 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.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Charles N. Rafferty, Ph.D., NIOSH Scientific Review Administrator, Bethesda, Maryland. Telephone (301)435–3562, E-mail *raffertc@csr.nih.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: May 21, 2001.

Carolyn J. Russell,

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

[FR Doc. 01–13237 Filed 5–24–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Statewide Automated Child Welfare Information System (SACWIS) Assessment Review GuidE (SARGE).

OMB No. 0970–0159.

Description: HHS cannot fulfill its obligation to effectively serve the nation's Adoption and Foster Care populations, nor report meaningful and reliable information to Congress about the extent of problems facing these children or the effectiveness of assistance provided to this population, without access to timely and accurate information. Currently, SACWIS systems support State efforts to meet the following Federal reporting requirements: the Adoption and Foster Care Analysis and Reporting System (AFCARS) required by section 479(b)(2) of the Social Security Act; the National Child Abuse and Neglect Data System (NCANDS); Child Abuse Prevention and Treatment Act (CAPTA); and the new Chafee Independent Living Program.

Forty-eight States and the District of Columbia have developed or have committed to develop a SACWIS system with Federal financial participation. The purpose of these reviews is to ensure that all aspects of the project, as described in the approved Advance Planning Document, have been adequately completed, and conform to applicable regulations and policies.

To initiate a review, States will submit the completed SACWIS Assessment Review GuidE (SARGE) and other documentation at the point that they have completed system development and the system is operational statewide. The additional documents submitted as part of this process should all be readily available to the State as a result of good project management.

The information collected in the SACWIS Assessment Review Guide will allow State and Federal officials to determine if the State's SACWIS system meets the requirements for title IV–E Federal financial participation defined at 45 CFR 1355.50. Additionally, other States will be able to use the documentation provided as part of this review process in their own system development efforts.

Respondents: State Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Review	6	1	200	1200
Estimated Total Annual Burden Hours				1200

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: May 22, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–13257 Filed 5–24–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic 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 June 7, 2001, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or by e-mail at SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss single patient use of nonapproved oncology drugs and biologics. This is a continuation of the discussion started at the December 13 and 14, 2000, meeting.

Procedure: The meeting is open to the public from 8 a.m. to 1 p.m. 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 May 31, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 31, 2001, 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.

Background materials for this meeting will be posted at the Oncologic Drugs Advisory Committee dockets Web site at www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to the Oncologic Drugs Advisory Committee meetings.) The slides and transcripts from the meeting will be posted at this same Web site about 3 weeks after the meeting.

Closed Committee Deliberations: The meeting will be closed from 1 p.m. to 5:30 p.m. to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

FDA regrets that it was unable to publish this notice 15 days prior to the May 23, 2001, Oncologic Drugs Advisory Committee meeting. Because there agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Dated: May 22, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–13368 Filed 5–23–01; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0087]

Guidance for Industry on IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information; 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 ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This guidance provides recommendations to industry on formal meetings between sponsors of investigational new drug applications (INDs) and the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) on chemistry, manufacturing, and controls (CMC) information.

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

ADDRESSES: Submit written requests for single copies of this 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 20852–1488, FAX 1–888–CBER–FAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Stephen K. Moore, Center for Drug Evaluation and Research (HFD–501), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430;

or

Robert A. Yetter, Center for Biologics and Research (HFM–10), Food and Drug Administration, Bldg. N29B, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This guidance covers three kinds of meetings held at specific times between sponsors and the agency where CMC issues are discussed: (1) Pre-IND, (2) end-of-phase 2, and (3) pre-new drug application or prebiologics license application. These meetings are used to address questions and scientific issues that arise during the course of clinical investigations, aid in the resolution of problems, and facilitate evaluation of the drug. The meetings often coincide with critical points in the drug development and/or regulatory process. This guidance is intended to assist in making these meetings more efficient and effective by providing information on the: (1) Purpose, (2) meeting request, (3) information package, (4) format, and (5) focus of the meeting.

In the **Federal Register** of February 4, 2000 (65 FR 5645), FDA announced the availability of a draft version of this guidance. The February 4, 2000, guidance gave interested persons an opportunity to submit comments through May 4, 2000. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on IND meetings for human drugs and biologics; chemistry, manufacturing, and controls information. 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