

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the prescribing officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by October 19, 2000, and the final decision of the Commission shall be issued by February 16, 2001.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 99-27869 Filed 10-25-99; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, November 1, 1999.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates

procedural and other information about the meeting.

Dated: October 22, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99-28098 Filed 10-22-99; 3:53 pm]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4396]

Draft Guidance for Industry on Financial Disclosure by Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Financial Disclosure by Clinical Investigators." This draft guidance provides clarification, and responds to questions, concerning implementation of the final rule issued by FDA requiring anyone who submits a marketing application for any drug, biologic, or device to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the final rule.

DATES: Submit written comments concerning this draft guidance by December 27, 1999.

ADDRESSES: Submit written requests for single copies of the guidance entitled "Financial Disclosure by Clinical Investigators" to Mary C. Gross, Office of International and Constituency Relations (HF-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20856. Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 10-61, Rockville, MD 20852. See the **Supplementary Information** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of International and Constituency Relations (HF-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20856, 301-827-3450, FAX 301-827-1335.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Financial Disclosure by Clinical Investigators." This draft guidance is intended to provide clarification concerning implementation of the final rule issued by FDA requiring anyone who submits a marketing application for any drug, biologic, or device to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the final rule. The requirements of the final rule took effect on February 2, 1999.

The agency's regulations on financial disclosure by clinical investigators require that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA are identified and disclosed by the applicant. This requirement applies to any clinical study submitted in a marketing application that the applicant or FDA relies on to establish that the product is effective and any study in which a single investigator makes a significant contribution to the demonstration of safety. Applicants are required to certify to the absence of certain financial interests of clinical investigators or to disclose those financial interests. If the applicant does not include a certification and/or disclosure or does not certify that it was not possible to obtain the information, the agency may refuse to file the application.

The agency has received many questions concerning implementation of this final rule and has issued this draft guidance in the form of questions and answers in an effort to respond to these questions. FDA wishes to emphasize its commitment to work with sponsors as they begin their efforts to comply with the provisions of the rule.

II. Electronic Access

Copies of this guidance are available on the Internet. The guidance is located at www.fda.gov/oc/guidance/financialdis.html.

III. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by December 27, 1999, to ensure adequate consideration in preparation of the final

document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-27840 Filed 10-25-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of November 1999:

Name: National Advisory Council on Migrant Health.

Date & Time: November 18, 1999—9:00 a.m.–5:30 p.m.; November 19, 1999—9:30 a.m.–10:30 a.m.; November 20, 1999—8:00 a.m.–11 a.m.

Place: Omni Colonnade Hotel, 180 Aragon Avenue, Coral Gables, Florida 33134, Phone: (305) 441-2600; Fax: (305) 445-3929.

The meeting is open to the public.

Agenda

This will be a meeting of the Council. The agenda includes an overview of general Council business activities and priorities. Topics of discussion will include the State Children's Health Insurance Program, Public Charge, the H-2 Guestworker Program, and including migrant workers in the Year 2000 Census. In addition, the Council will be holding its annual Farmworker Public Hearing. The Hearing is scheduled for Saturday, November 20, from 8 a.m. to 11 a.m. at the Omni Colonnade. The Council meeting is being held in conjunction with the 12th Annual East Coast Migrant Stream

Forum, November 19–21, 1999. The Stream Forum also will take place at the Omni Colonnade, Coral Gables, Florida.

Anyone requiring information regarding the subject Council should contact Judy Rodgers, Migrant Health Program, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone 301/594-4304.

Agenda items are subject to change as priorities indicate.

Dated: October 20, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99-27841 Filed 10-25-99; 8:45 am]

BILLING CODE 4160-15-P

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 (301) 443-7978.

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: Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families—Phase III—(New)

The national evaluation of SAMHSA's Comprehensive Community Mental Health Services for Children and Their Families Program will collect data on child mental health outcomes, family life, and service system implementation and development. Data will be collected on 21 service systems (20 funded systems of care and one comparison site), and on approximately 5766 children and families. Data collection for this evaluation will be conducted over a five-year period. The core of the service system data will be collected every 18 months throughout the five-year evaluation period, with a provider survey conducted in selected years.

Service delivery and system variables of interest include the following: system of care development, adherence to the system of care program model, and client service experience. The length of time that individual families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation. Child and family outcomes will be collected at intake and during subsequent follow-up sessions at six-month intervals. The outcome measures include the following: child symptomatology and functioning, family functioning, material resources, and caregiver strain. In addition, a treatment effectiveness study will examine the relative impact of an evidence-based treatment within one system of care. Internet-based technology will be used for data entry and management. The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent each year, the average length of time it will take for each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.

Respondent	Number of respondents	Responses/ respondent	Average burden/re-sponse (hrs.)	Total average annual burden
Caregiver	5,766	1.11	2.25	14,400.59
Youth	3,460	1.06	0.92	3,374.19
Provider/Administrator	420	0.52	1.32	288.29
Total	9,646	18,063.07