I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 21(a) of the Occupational Safety and Health Act [29 U.S.C. 670(a)]. Regulations applicable to this Program are in 42 CFR 86, ''Grants for Education Programs in Occupational Safety and Health''. The Catalog of Federal Domestic Assistance number is 93.263.

J. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC home page is: *http://www.cdc.gov.*

Please refer to Program Announcement 01035 when you request information. To receive additional written information and to request application materials call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01035, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2724, Email address: *svp1@cdc.gov.*

For program technical assistance, contact: Bernadine Kuchinski, Occupational Health Consultant, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, N.E., Mailstop D–40, Atlanta, Georgia 30341, Telephone (404) 639–3342, Email address: bbk1@cdc.gov

Dated: March 21, 2001.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–7585 Filed 3–27–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Fourth Annual Educational Workshop––Current Topics in Regulatory Affairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), in cosponsorship with the Orange County Regulatory Affairs (OCRA) discussion group, is announcing its Fourth Annual Educational Workshop intended to give the drugs, devices, and biologics industries an opportunity to interact with FDA's reviewers and compliance officers from FDA's centers and district offices. The main focus of this interactive workshop is to provide regulatory updates, guidances, and recommendations regarding new product submissions, postapproval changes, and postmarketing issues.

Date and Time: The meeting will be held on May 21 and 22, 2001, 7:30 a.m. to 5 p.m.

Location: The meeting will be held at The Irvine Marriott, 18000 Von Karman Ave., Irvine, CA.

Contact: Ramlah I. Oma, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7611, FAX: 949–798–7656, or Peri Ann DiRocco, OCRA discussion group, PMB 624, 5405 Alton Pkwy., suite 5A, Irvine, CA 92604, voice/FAX: 949–348–9141, e–mail: sdirocco@aol.com, www.ocra-dg.org.

Registration and Requests for Oral Presentations: Space is limited. Preregistration and confirmation are required. Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations directly to the OCRA Web site.

If you need special accommodations due to a disability, please contact Ramlah I. Oma at least 10 days in advance.

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

Dated: March 20, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–7565 Filed 3–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4396]

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 a guidance entitled ''Financial Disclosure by Clinical Investigators.'' FDA published a final rule 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 rule. These requirements took effect on February 2, 1999. This guidance is intended to provide clarification and respond to questions and comments concerning implementation of the final rule.

DATES: Submit written comments at any time.

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 20857. Send a self-addressed adhesive label to assist that 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.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of International and Constituency Relations (HF–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3450.

SUPPLEMENTARY INFORMATION:

I. Background

The financial disclosure by clinical investigators regulations 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 absences of certain financial interests of clinical investigators or to disclose those financial interests. If the applicant does not include certifications and/or disclosure or does not certify that it was not possible to obtain the information, the agency may refuse to file the application.

II. Discussion of Comments

The agency has received 12 comments on the draft guidance which published in the **Federal Register** of October 26, 1999 (64 FR 57640). Some commenters asked whether use of Forms FDA 3454 and 3455 is mandatory. One comment asked how much information should be submitted when incomplete financial information is known. There were numerous commenters who asked whether information could be submitted through a questionnaire instead of through internal systems. Some commenters requested clarification on what FDA meant by the definition of ''sponsor of the covered study.'' Comments were received on whether travel expenses for investigators should be tracked as significant payments of other sorts. Several commenters asked for clarification on FDA's definition of clinical investigator and subinvestigators. A few comments discussed the need to allow exemption for large scale efficacy studies from the covered clinical study definition. There were also comments requesting clarification on what FDA means by completion of the study and 1 year following completion of the study.

III. Status of the Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on financial disclosure by clinical investigators. 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 requirement of the applicable statutes and regulations.

IV. Electronic Access

Persons interested in obtaining a copy of the guidance on the Internet may access the guidance at http://internet-dev.fda.gov/oc/guidance/finsumm.html or http://www.fda.gov/ohrms/dockets/default.htm.

V. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance 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: March 20, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–7564 Filed 3–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–4020–N]

Medicare Program; Renewal of the Advisory Panel for Medicare Education (APME)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the renewal of the Advisory Panel on Medicare Education (the Panel or APME). The Panel advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Health Care Financing Administration (the Administrator) concerning optimal strategies for implementing a national Medicare education program; enhancing the Federal Government's effectiveness in informing the Medicare consumer; expanding outreach to vulnerable and under-served communities; and assembling an information base of ''best practices'' for helping consumers to evaluate health plan options and build a community infrastructure for information, counseling, and assistance. In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, this notice announces the signing of the APME charter renewal by the Secretary on January 18, 2001. The charter will terminate on January 21, 2003, unless renewed by the Secretary.

FOR FURTHER INFORMATION CONTACT: Nancy Caliman, Partnership Development Group, Center for Beneficiary Services, HCFA, 7500 Security Boulevard, Mail Stop S2–23–05, Baltimore, MD 21244, (410) 786–5052, or E-mail ncaliman@hcfa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On February 17, 1999, we published a notice in the **Federal Register** (64 FR 7899) announcing the establishment of the Citizens Advisory Panel on Medicare Education. The Secretary signed the charter for the Citizens Advisory Panel on Medicare Education on January 21, 1999. The name of the committee was changed to the Advisory Panel on Medicare Education via an amended charter signed by the Secretary on July 24, 2000.

The Panel, chartered under section 1114(f) of the Social Security Act (42 U.S.C. section 1314(f)), is governed by the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2), that set forth standards for the formation and use of advisory committees.

The Panel consists of up to 20 members with expertise in senior citizen advocacy; outreach to minority communities; health communications; disease-related health advocacy; disability policy and access; health research; health insurers and plans; providers and clinicians; and matters of labor and retirement. There are currently 16 members on the Panel.

The Panel advises the Secretary and the Administrator concerning optimal strategies for—

- Developing and implementing a national Medicare education program that describes the options for selecting a health plan under Medicare;
- Enhancing the Federal Government's effectiveness in informing the Medicare consumer, including providing information about the appropriate use of public-private partnerships;
- Expanding outreach to vulnerable and under-served communities, including racial and ethnic minorities, in the context of a national Medicare education program; and,
- Assembling an information base of ''best practices'' for helping consumers to evaluate health plan options and build a community infrastructure for information, counseling and assistance.

II. Provisions of This Notice

This notice announces the signing of the APME charter renewal by the Secretary on January 18, 2001. The charter will terminate on January 21, 2003, unless renewed by appropriate action before its expiration date.