

## 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](mailto: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](mailto: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).*

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## 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](mailto:sdirocco@aol.com), [www.ocra-dg.org](http://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.*

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## 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