

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4396]

9450 '01 MAR 26 11 45 AM '01

Display Date	3/27/01
Publication Date	3/28/01
Certifier	W. M. O'Leary

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:

oc00139

NAD2

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

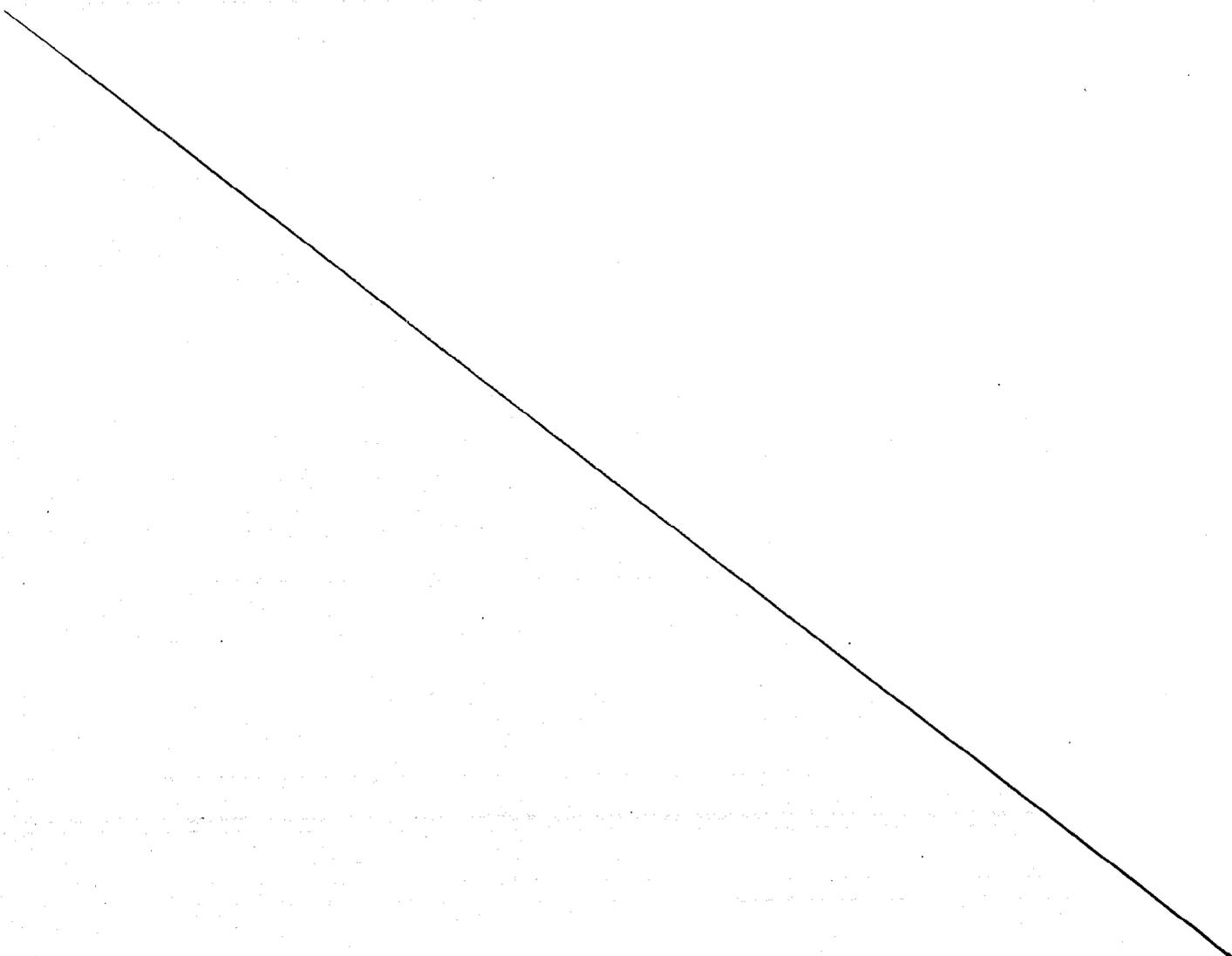
The agency has received 12 comments on the draft guidance which published in the **Federal Register** of October 26, 1999 (64 FR 57640). Some commenters asked whether use of Forms FDA 3454 and 3455 is mandatory. One comment asked how much information should be submitted when incomplete financial information 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>.



JS

IV. 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
March 20, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Ronnie Oliver

Ann M. Witt

Ann M. Witt,
Acting Associate ~~for~~ Commissioner ~~for~~ Policy.

JS

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S