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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	J. W. [Signature]

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**Draft Guidance for Industry on Financial Disclosure by Clinical Investigators;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Financial Disclosure by Clinical Investigators." This draft guidance provides clarification, and responds to questions, concerning implementation of the final rule issued by FDA requiring anyone who submits a marketing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DATES: Submit written comments concerning this draft guidance by *(insert 60 days after date of publication in the Federal Register)*.

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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 10-61, Rockville, MD 20852. See the **Supplementary Information** section of this document for electronic access to the draft guidance.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 This draft guidance is intended to provide clarification concerning implementation of the final rule issued by FDA requiring anyone who submits a marketing application for any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.

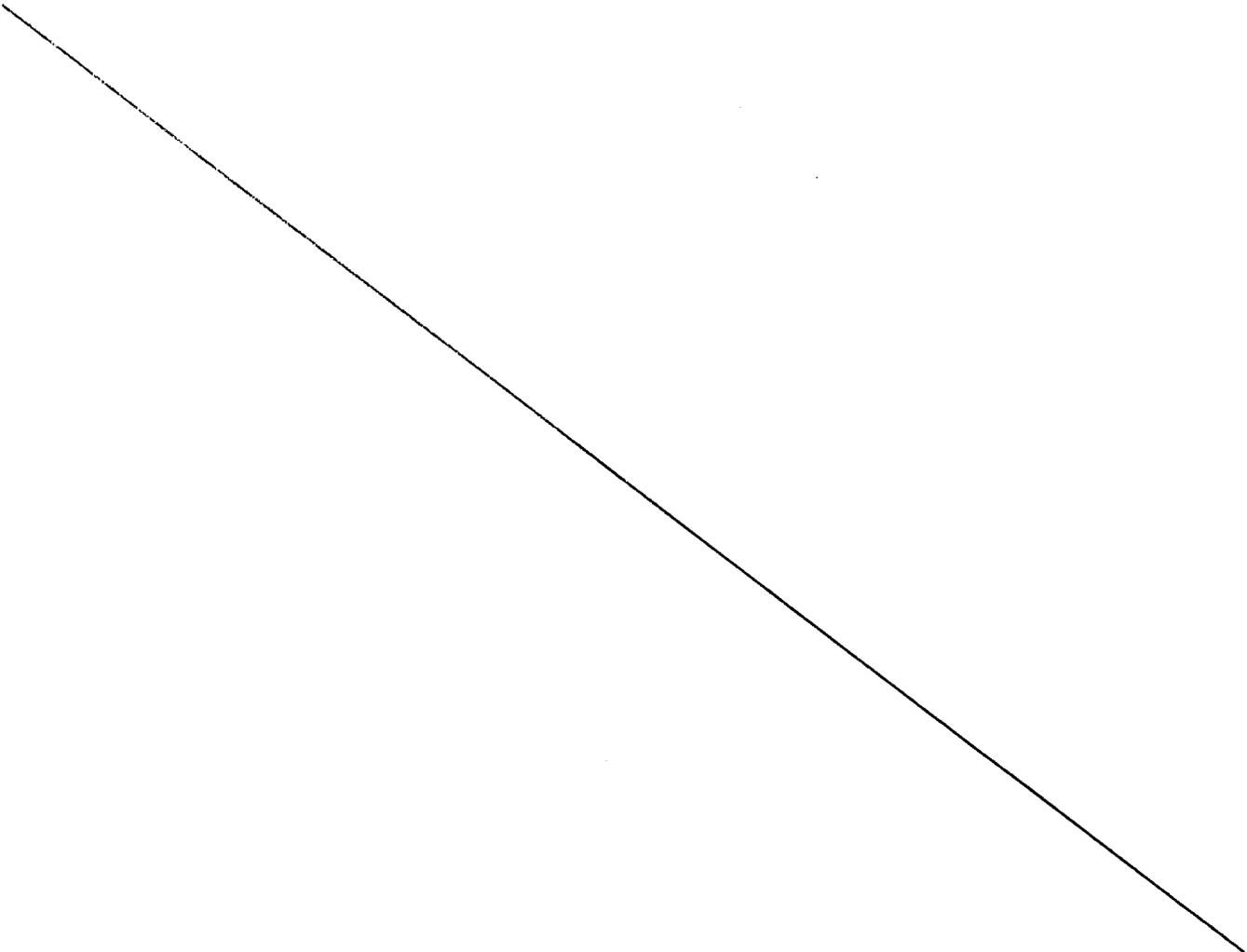
The agency has received many questions concerning implementation of this final rule and has issued this draft guidance in the form of questions and answers in an effort to respond to these questions. FDA wishes to emphasize its commitment to work with sponsors as they begin their efforts to comply with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

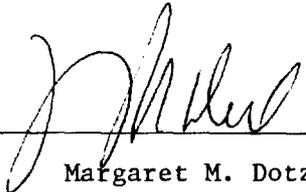
This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by *(insert date 60 days after date of publication in the **Federal Register**)*, 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: 10/19/99
October 19, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Margaret M. Dotzel
Acting Associate Commissioner for Policy



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