

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0079]

DMB 3-12-01

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Certifier	<i>TJ</i>

Acceptance of Foreign Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled "Acceptance of Foreign Clinical Studies." This final guidance is intended to clarify the ethical principles with which a sponsor must comply before FDA would accept a foreign clinical study not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) in support of a marketing approval application.

DATES: Submit written comments on the final guidance at any time.

ADDRESSES: Submit written requests for single copies of the final guidance entitled "Acceptance of Foreign Clinical Studies" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels 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. 1601, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the final guidance.

FOR FURTHER INFORMATION CONTACT: David A. Lepay, Office for Science Coordination and Communication (HF-34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4000.

SUPPLEMENTARY INFORMATION:

NAB I

I. Background

FDA regulations allow for the acceptance of foreign clinical studies not performed under an IND or IDE in support of a marketing approval application for a drug, biological product, or device if certain conditions are met. Under these regulations, the study must conform to the ethical principles contained in the Declaration of Helsinki (the Declaration) or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. In October 2000, the World Medical Association approved a fifth revision of the Declaration. FDA is making this guidance available to clarify which version of the Declaration was incorporated into the drug regulations, and which version of the Declaration was incorporated into the device regulations, and, therefore, which version of the Declaration is applicable to foreign studies conducted without an IND or IDE. FDA will also review any other guidance documents on this subject, and modify them, if necessary, to conform to the clarification expressed in this guidance.

II. Significance of Guidance

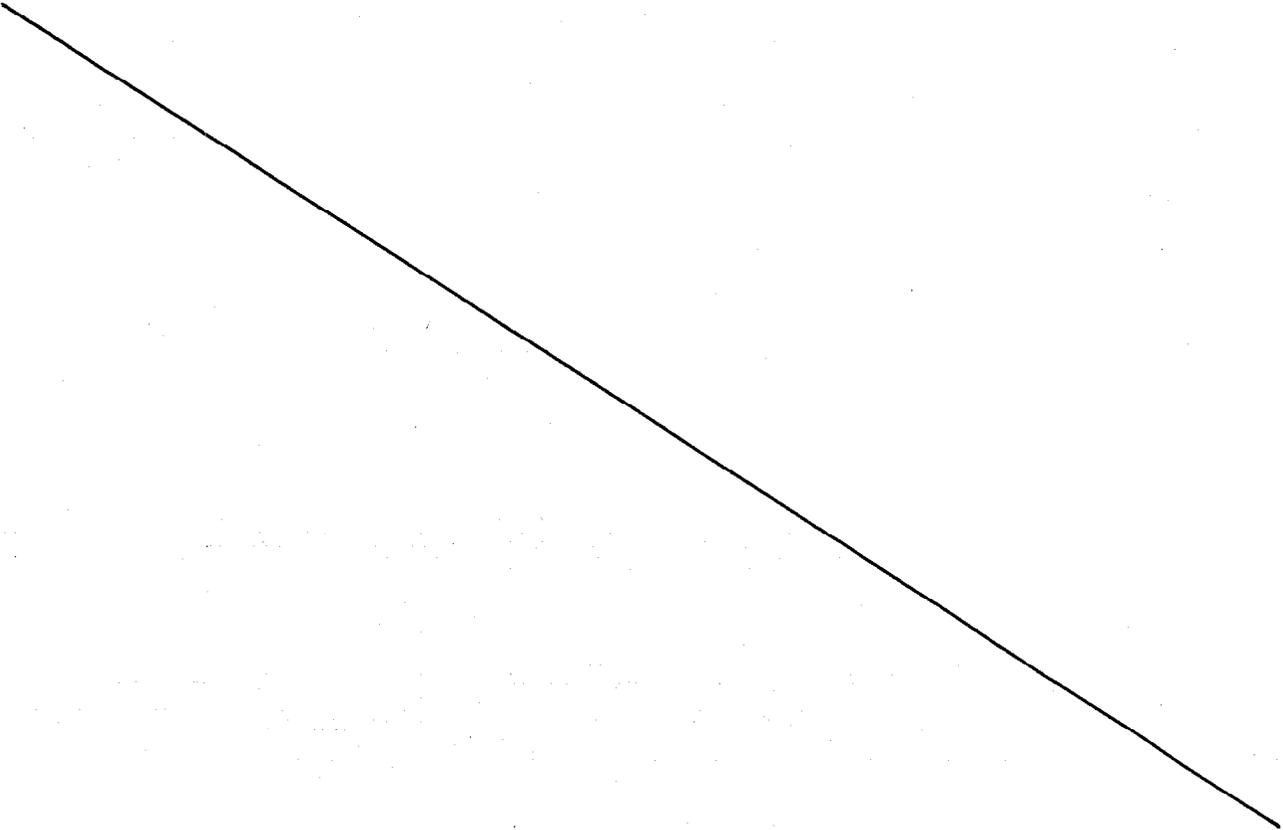
This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the ethical principles with which a sponsor must comply before FDA would accept a foreign clinical study not conducted under an IND or IDE in support of a marketing approval application. 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 requirements of the applicable statutes and regulations.

Under FDA's good guidance practice regulations, this guidance is being issued as a Level 2 guidance because it sets forth the agency's existing practices (21 CFR 10.115(c)(2); 65 FR 56468, September 19, 2000). Therefore, FDA is issuing this document as a final guidance prior to receiving public comment. However, as with all FDA guidance, the public is encouraged to submit written

comments with new data or other new information pertinent to this guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended.

III. Comments

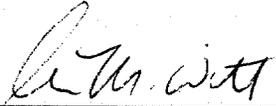
Interested persons may, at any time, submit written comments on the final guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The final guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

Persons with access to the Internet may obtain this guidance at <http://www.fda.gov/cder>.

Dated: March 5, 2001
March 5, 2001



Ann M. Witt
Acting Associate Commissioner for Policy

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



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

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