

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0087]

Display Date	5-24-01
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Certifier	Romona Oliver

Guidance for Industry on IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information." This guidance provides recommendations to industry on formal meetings between sponsors of investigational new drug applications (INDs) and the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) on chemistry, manufacturing, and controls (CMC) information.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1488, FAX 1-888-CBER-FAX or 301-827-3844. Send one self-addressed adhesive label to assist the 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

NAD 2

Stephen K. Moore, Center for Drug Evaluation and Research (HFD-501), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6430;

or

Robert A. Yetter, Center for Biologics and Research (HFM-10), Food and Drug Administration, Bldg. N29B, 8800 Rockville Pike, Bethesda, MD 20892, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information." This guidance covers three kinds of meetings held at specific times between sponsors and the agency where CMC issues are discussed: (1) Pre-IND, (2) end-of-phase 2, and (3) pre-new drug application or prebiologics license application. These meetings are used to address questions and scientific issues that arise during the course of clinical investigations, aid in the resolution of problems, and facilitate evaluation of the drug. The meetings often coincide with critical points in the drug development and/or regulatory process. This guidance is intended to assist in making these meetings more efficient and effective by providing information on the: (1) Purpose, (2) meeting request, (3) information package, (4) format, and (5) focus of the meeting.

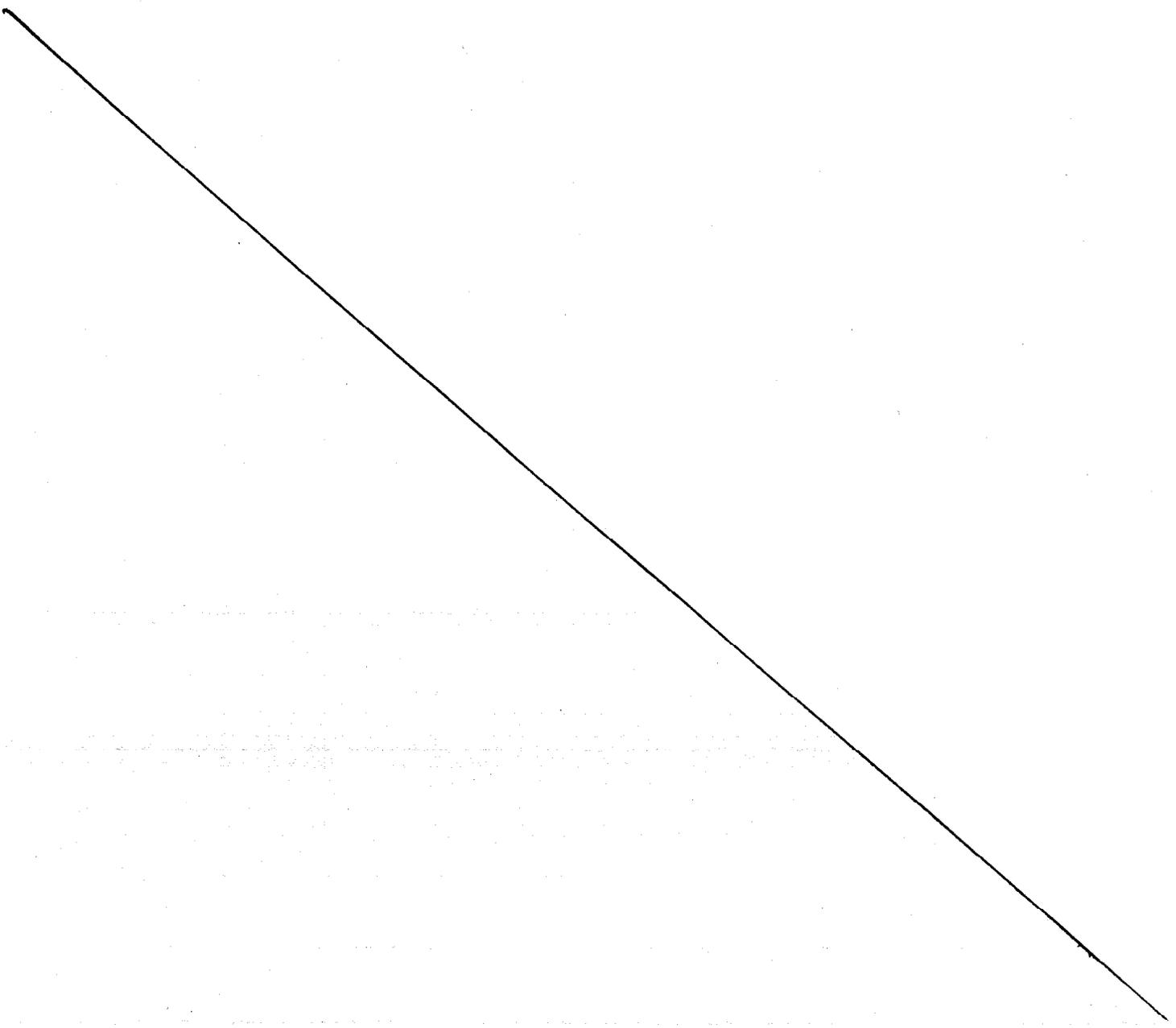
In the **Federal Register** of February 4, 2000 (65 FR 5645), FDA announced the availability of a draft version of this guidance. The February 4, 2000, guidance gave interested persons an opportunity to submit comments through May 4, 2000. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version.

This level 1 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 IND meetings for human drugs and biologics; chemistry, manufacturing, and controls information. 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.

II. Comments

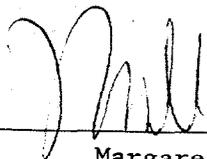
Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 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.



III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/ohrms/dockets/default.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: 5/17/01
May 17, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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

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

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