

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0674]

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Certifier R. WEDESMA

Guidance for Industry on INDs for Phase 2 and Phase 3 Studies; 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 "INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information." This guidance is intended to provide recommendations to sponsors of investigational new drug applications (INDs) on the chemistry, manufacturing, and controls documentation (CMC), including microbiology documentation, that should be submitted for phase 2 and 3 studies conducted under INDs. The guidance applies to human drugs (as defined in the Federal Food, Drug, and Cosmetic Act). The guidance does not apply to botanical drug products, protein drugs derived from natural sources or produced by the use of biotechnology, or other biologics.

DATES: Submit written or electronic 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. Send one 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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Charles Hoiberg, Center for Drug Evaluation and Research (HFD-800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information.” The guidance is intended to: (1) Ensure that sufficient data will be submitted to the agency to assess from the CMC perspective the safety and quality of the proposed clinical studies; (2) expedite the entry of new drugs into the marketplace by clarifying the type, extent, and reporting of CMC information for phase 2 and 3 studies; and (3) facilitate drug discovery and development.

In the **Federal Register** of April 21, 1999 (64 FR 19543), FDA announced the availability of a draft version of this guidance entitled “INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format.” The April 1999 guidance gave interested persons an opportunity to submit comments through July 20, 1999. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. The format of the guidance has been reorganized

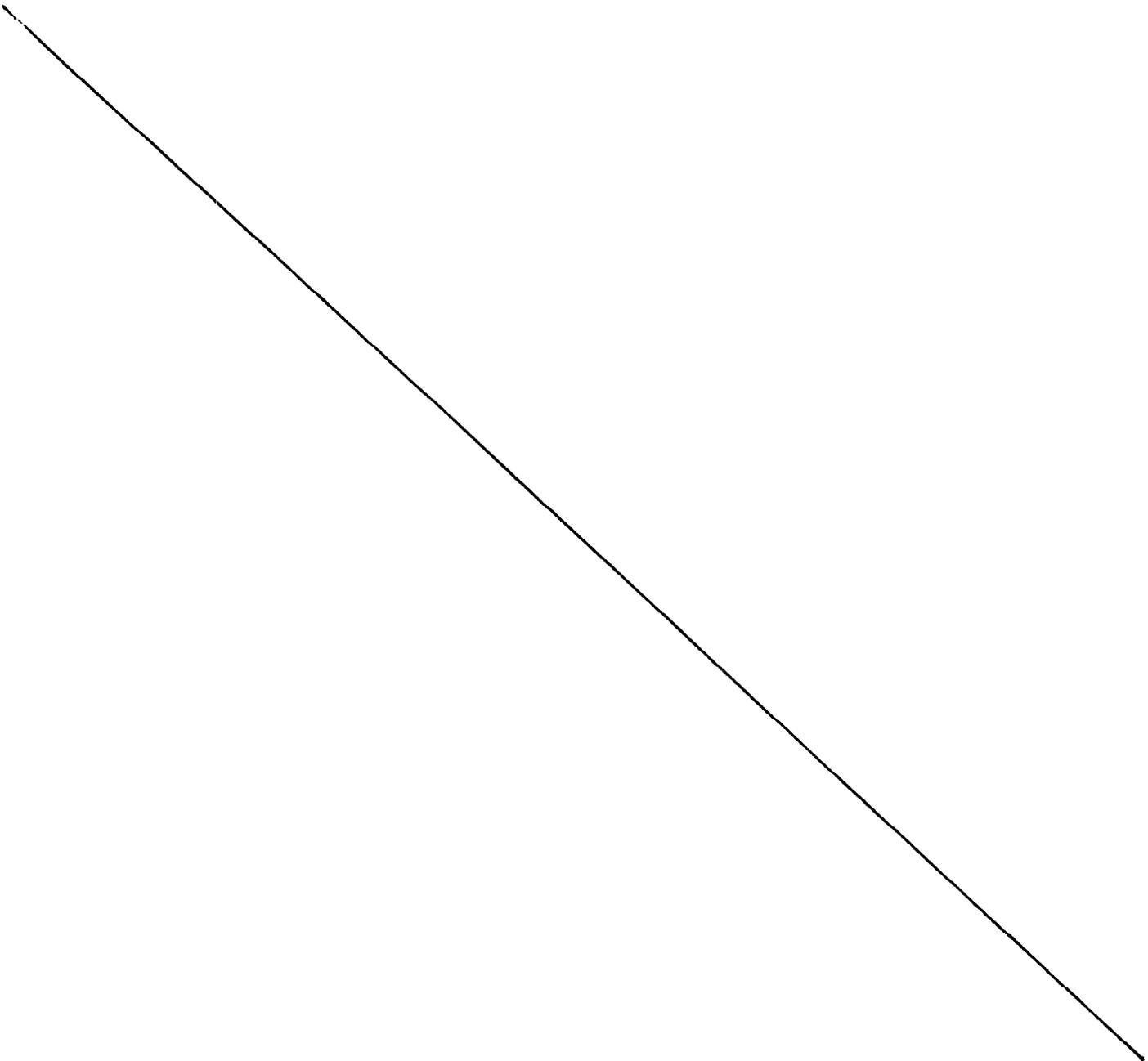
to include the relevant headings and to follow the order recommended for an application submitted in the “Common Technical Document: Quality” format (see the Quality section of the guidance entitled “M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use” that FDA announced in the **Federal Register** on October 16, 2001 (66 FR 52634)). Additional information has been included to explain the difference between CMC safety information, which should be submitted in an information amendment, and corroborating information that can be submitted in an annual report. As a result of the public comments and editorial changes, the guidance is clearer and more concise than the draft version. Furthermore, the scope of the guidance has been changed to exclude proteins and biologics. The agency is considering developing a separate guidance on INDs for these types of drugs.

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB Control No. 0910–0014.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on CMC content and format of INDs for phase 2 and 3 studies of certain drugs. 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 submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

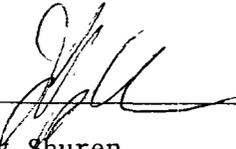


III. Electronic Access

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

Dated: 5/13/03

May 13, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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