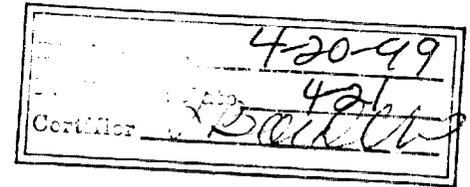


DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration



[Docket No. 99D-0674]

**Draft Guidance for Industry on IND's for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format." This draft guidance is intended to provide recommendations to sponsors of investigational new drug applications (IND's) on the chemistry, manufacturing, and controls documentation (CMC), including microbiology documentation, that should be submitted for phase 2 and 3 of IND's. This draft guidance applies to human drugs and specified-biotechnology derived products.

**DATES:** Written comments on the draft guidance document may be submitted by (*insert date 90 days after date of publication in the Federal Register*). General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or 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 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY**

**INFORMATION** section for electronic access to the draft. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2570, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

**SUPPLEMENTARY INFORMATION:**

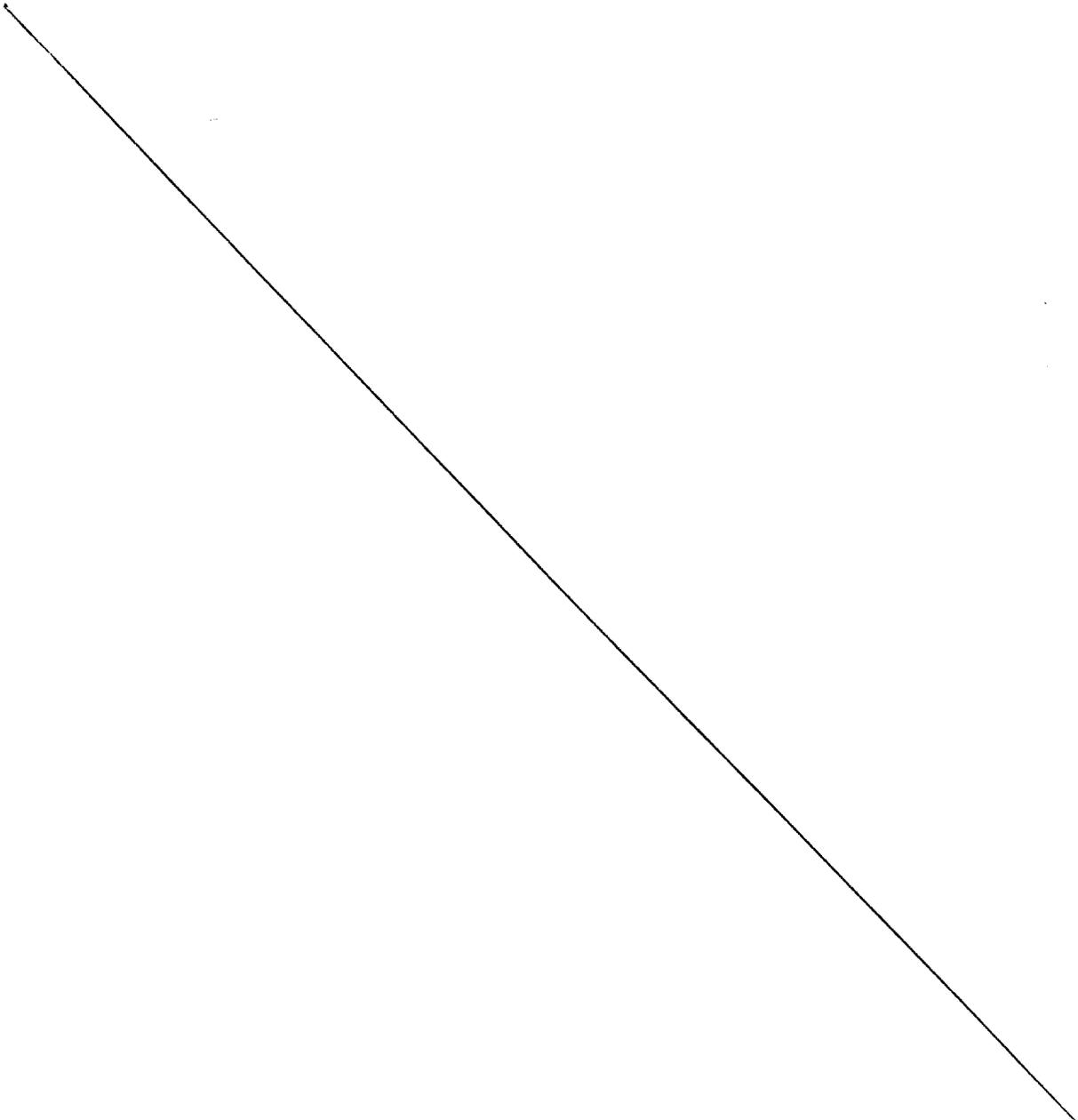
**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format.” This draft guidance is intended to: (1) Facilitate drug discovery and development, (2) ensure that sufficient data will be submitted for the agency to assess the safety as well as the quality of the proposed clinical studies from the CMC and microbiology perspectives, and (3) expedite the entry of new drugs into the marketplace.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). This draft guidance represents the agency’s current thinking on CMC content and format of IND’s for phase 2 and 3 studies of drugs, including specified therapeutic biotechnology-derived products. 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 statute, regulations, or both.

**II. Comments**

Interested persons may submit written comments on the draft 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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

Copies of this draft guidance are available on the Internet at “<http://www.fda.gov/cder/guidance/index.htm>” or “<http://www.fda.gov/cber/guidelines.htm>”.

Dated: April 12, 1999

April 13, 1999



---

William K. Hubbard  
Acting Deputy Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

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

