

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2005-D-0157] (formerly Docket No. 2005D-0286)

### Guidance for Industry: Current Good Manufacturing Practice for Phase 1 Investigational Drugs; Availability

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: CGMP for Phase 1 Investigational Drugs” dated July 2008. The guidance provides assistance in applying relevant current good manufacturing practice (CGMP) requirements of the Federal Food, Drug, and Cosmetic Act (the act) to the manufacture of most investigational new drugs, including biological drugs, used in phase 1 clinical trials. FDA is issuing this guidance concurrently with a final rule published elsewhere in this issue of the **Federal Register** specifying that compliance with FDA’s CGMP regulations is not required for most investigational drugs that are manufactured for use in phase 1 clinical trials. Therefore, FDA is recommending the approaches outlined in this guidance for complying with the statutory CGMP requirements in the act. The guidance announced in this notice finalizes the draft guidance entitled “INDs—Approaches to Complying with CGMP During Phase 1” dated January 2006.

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

**ADDRESSES:** Submit written requests for single copies of the 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 the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9047, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5000.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled “Guidance for Industry: CGMP for Phase 1 Investigational Drugs” dated July 2008. This guidance provides assistance in applying CGMP required under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) in the manufacture of most

investigational new drugs used in phase 1 clinical trials (phase 1 investigational drugs). The guidance is being issued concurrently with a final rule that specifies that the manufacture of most investigational new drugs manufactured for use in phase 1 clinical trials do not have to comply with the specific regulatory requirements in part 211 (21 CFR part 211).

Because a phase 1 clinical trial initially introduces an investigational new drug into human subjects, appropriate CGMP helps ensure subject safety. This guidance applies, as part of CGMP, quality control principles to the manufacture of phase 1 investigational drugs (i.e., interpreting and implementing CGMP consistent with good scientific methodology), which foster CGMP activities that are more appropriate for phase 1 clinical trials, improve the quality of phase 1 investigational drugs, and facilitate the initiation of investigational clinical trials in humans while continuing to protect trial subjects. For the manufacture of phase 1 investigational drugs described in this guidance (see section III of the guidance), this guidance will replace the guidance issued in 1991 (56 FR 7048, February 21, 1991) entitled “Preparation of Investigational New Drug Products (Human and Animal)” (the 1991 guidance). However, the 1991 guidance still applies to the manufacture of investigational new products (human and animal) used in phase 2 and phase 3 clinical trials.

In the **Federal Register** of January 17, 2006 (71 FR 2552), FDA announced the availability of the draft guidance entitled “INDs—Approaches to Complying with CGMP During Phase 1” dated January 2006. FDA received a moderate number of comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated January 2006.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 for part 211 have been approved under OMB control number 0910–0139.

## **III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding 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. A copy of the guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

**IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: July 9, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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