

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	<i>S. N. Kelle</i>

Food and Drug Administration

[Docket No. 98D-0282]

Revised Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled "Submitting and Reviewing Complete Responses to Clinical Holds." This guidance describes how to submit a complete response if an investigational new drug (IND) application is placed on clinical hold. The revised guidance reflects amendments to FDA's clinical hold regulations, includes the definition of a commercial IND, and discusses the agency's policy on resolving clinical trial issues that are not related to the imposition of a clinical hold.

DATES: Comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>; or <http://www.fda.gov/cber/guidelines.htm>. Submit written comments on this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Linda S. Carter (HFD-101), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6578; or Robert A. Yetter (HFM-10), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a revised guidance for industry entitled "Submitting and Reviewing Complete Responses to Clinical Holds." Section 117 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), signed into law by President Clinton on November 21, 1997, provides that a written request that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. Section 117(3)(c) of the Modernization Act is codified in the Federal Food, Drug, and Cosmetic Act at section 505(i)(3)(c) (21 U.S.C. 355(i)(3)(c)). In addition, the agency committed to user fee performance goals incorporating the same response time. In the **Federal Register** of December 14, 1998 (63 FR 68676), FDA amended its clinical hold regulations in § 312.42(e) (21 CFR 312.42(e)) to include this 30-day response requirement. This guidance describes how sponsors should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to response.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA published a notice announcing the availability of the original guidance and soliciting comments. Two comments on the guidance were submitted to the docket. After considering the comments, FDA is issuing a revised guidance.

The revised guidance: (1) Reflects amendments to FDA's clinical hold regulations, stating that FDA will respond in writing within 30-calendar days of receipt of a sponsor's request to release a clinical hold and complete response to the issue(s) that led to the clinical hold (§ 312.42(e)); (2) includes the definition of a commercial IND and clarifies that the Prescription Drug User Fee Act goals apply only to commercial IND's, although the 30-calendar day response applies to all IND clinical hold complete responses; and (3) states that clinical trial issues that are not related to the imposition of a clinical hold may be discussed in the letter placing the trial on clinical hold, but will be clearly marked as nonhold issues and that a sponsor's response to such nonhold issues should be addressed in a separate amendment to the IND.

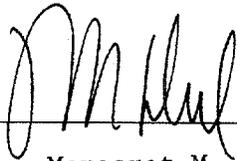
The collection of information contained in the revised guidance has been approved by the Office of Management and Budget under OMB control number 0910-0445.

This revised guidance document supersedes the original guidance. This Level 1 guidance document is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The revised guidance represents the agency's current thinking on the submission of responses to clinical holds. 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 and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance at any time. 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.

Dated: 10/13/00
October 13, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

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