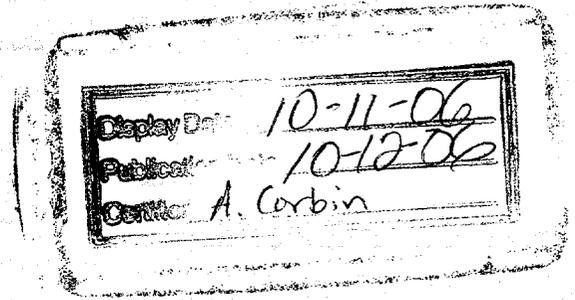


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D-0777] (formerly Docket No. 98D-0777)



**Guidance for Industry on Investigating Out-of-Specification Test Results for
Pharmaceutical Production; 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 "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production." This guidance provides information for the pharmaceutical industry on how to evaluate laboratory test results that fall outside of specification limits. The guidance is intended to provide clear and consistent communication of regulatory expectations and to promote voluntary compliance with current FDA requirements.

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 Division of Dockets Management (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: Paul W. Haynie, Center for Drug Evaluation and Research (HFD-327), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-9020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production.” This guidance document provides guidance to the pharmaceutical industry on investigation of laboratory results that fall outside of specification limits. The guidance addresses investigations of OOS results in the laboratory phase, including responsibilities of the analyst and supervisor, and when indicated, the expansion of an investigation outside of the laboratory to include production processes, and raw materials as appropriate. This guidance is intended to apply to traditional methods of drug product testing and release, based on testing of discrete samples of in-process materials and finished products. The guidance is not intended to address process analytical technology, as routine in-process use of these methods might include other considerations. The agency, in accordance with its August 2002 “Pharmaceutical CGMPs for the 21st Century” initiative, encourages modern approaches to manufacturing, monitoring, and control to enhance process predictability and efficiency. The use of continuous on-line testing technologies will be addressed in other agency guidance.

In the **Federal Register** of September 30, 1998 (63 FR 52276), FDA announced the availability of a draft guidance of the same title and gave

interested persons an opportunity to submit comments by November 30, 1998. The agency received public comments from a broad spectrum of the pharmaceutical industry. In response to comments received on the draft guidance, the agency made the following changes: (1) Revised the scope and background sections to clarify the applicability of the document, (2) reorganized the sections on investigating OOS results, averaging, and concluding the investigation, and (3) clarified or added more specific guidance on certain issues.

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 investigating OOS test results for pharmaceutical production. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management 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: 10/3/06
October 3, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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