

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004D-0494]

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Certifier R. JED ESMA

DDH

**Guidance for Industry on Changes to an Approved New Drug Application  
or Abbreviated New Drug Application; Specifications—Use of Enforcement  
Discretion for Compendial Changes**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Changes to an Approved NDA or ANDA; Specifications—Use of Enforcement Discretion for Compendial Changes.” This guidance informs new drug application (NDA) and abbreviated new drug application (ANDA) holders of FDA’s plan to use enforcement discretion with regard to the regulation on changes to an approved application. This regulation describes the filing requirement that a relaxation of acceptance criteria or deletion of a test to comply with an official compendium must be reported in a changes-being-effected-in-30-days supplement (CBE-30). FDA does not intend to take enforcement action if manufacturers continue to submit such changes in their annual reports. The use of enforcement discretion will give the agency time to clarify that some of these types of postapproval changes can be submitted in an annual report, rather than in a CBE-30. The agency intends to clarify this issue in an upcoming revision to a guidance for industry.

**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>. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** David J. Cummings, Center for Drug Evaluation and Research (HFD-357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5187.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of April 8, 2004 (69 FR 18728), FDA published a final rule entitled "Supplements and Other Changes to an Approved Application." In the same issue of the **Federal Register** (69 FR 18768), FDA announced the availability of the guidance for industry entitled "Changes to an Approved NDA or ANDA" (the changes guidance). Under § 314.70(c)(2)(iii) (21 CFR 314.70(c)(2)(iii)) of the final rule, the relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements must be submitted as a CBE-30 (see section VIII.C.1.e of the changes guidance).

FDA is issuing this guidance to explain that it is using enforcement discretion with regard to § 314.70(c)(2)(iii) to address concerns raised by stakeholders. FDA plans to clarify that some of these types of changes can be submitted in an annual report, instead of a CBE-30 supplement, in a revision of the guidance for industry entitled “Changes to an Approved NDA or ANDA; Questions and Answers.”

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 collection of information in this guidance was approved under OMB Control No. 0910–0001 and 0910–0032.

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 these topics. 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.

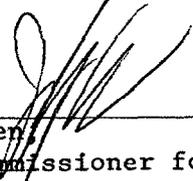
## **II. Comments**

Interested persons may at any time submit to the Division of Dockets Management written or electronic comments on the guidance (see **ADDRESSES**). 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 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: 11/13/04  
November 13, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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