

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D-0529]

Guidance for Industry on Changes to an Approved NDA or ANDA; 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 "Changes to an Approved NDA or ANDA." The guidance has been revised to conform to the final rule amending the agency's regulations on changes to an approved NDA or ANDA published elsewhere in this issue of the **Federal Register**. The guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or an abbreviated new drug application (ANDA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the 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. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD-357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5633. The e-mail address for

questions about content of the guidance is pac314_70@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105-115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. The agency's final rule amending its regulations at § 314.70 (21 CFR 314.70) to implement section 506A of the act is published elsewhere in this issue of the **Federal Register**.

FDA is announcing the availability of a revised guidance for industry entitled "Changes to an Approved NDA or ANDA." In the **Federal Register** of November 23, 1999 (64 FR 65716), FDA announced the availability of a guidance of the same title (November 1999 guidance). The November 1999 guidance has been revised to conform to the final rule amending § 314.70 and to include nonsubstantive corrections and clarifications. This revised guidance supersedes the November 1999 guidance.

The purpose of the guidance is to provide recommendations to holders of NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act and § 314.70. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in the following areas: (1) Components and composition, (2) manufacturing sites, (3) manufacturing process, (4) specifications, (5) container closure system, (6) labeling, (7) miscellaneous changes, and (8) multiple related changes. The guidance does not provide recommendations on the specific information that should be developed

by the applicant to assess the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as these factors may relate to the safety or effectiveness of the product.

This level 1 guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. Insofar as this guidance adjusts reporting categories under section 506A of the act and § 314.70, it does have binding effect.

FDA has established an e-mail address where applicants can send questions about the content of the guidance (see **FOR FURTHER INFORMATION CONTACT**), such as requests for clarification of information in the guidance or requests for guidance on the reporting category for a particular change the applicant wants to implement.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) 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 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: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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