

Display Date	6-25-99
Publication Date	6-28-99
Certifier	Mark W. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

0574 '98 OCT 22 A6:26

[Docket No. 99D-0529]

**Draft Guidance for Industry on Changes to an Approved NDA or ANDA; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Changes to an Approved NDA or ANDA." This draft guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under the proposed revision to the drug regulations pertaining to supplements and other changes to an approved application published elsewhere in this issue of the **Federal Register**.

**DATES:** Written comments may be submitted on the draft guidance document by (*insert date 60 days after date of publication in the Federal Register*). General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>". Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled “Changes to an Approved New Drug (NDA) or Abbreviated New Drug (ANDA) Application.”

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Pub. L. 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. FDA is proposing to amend its regulations entitled *Supplements and other changes to an approved application* at § 314.70 (21 CFR 314.70) to conform to section 506A of the act. This proposed rule is published elsewhere in this issue of the **Federal Register**.

The purpose of this draft 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 the proposed amended regulations at § 314.70. This draft 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: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes. This guidance does not provide recommendations on the specific information that should be developed by the applicant to validate 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 they may relate to the safety or effectiveness of the product.

The guidance document, which cites the proposed rule for amending § 314.70, will be revised based on public comments and implemented for use as a companion document to § 314.70 when the rule is finalized. FDA welcomes comments that provide additional examples of major, moderate, and minor changes.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This guidance document represents the agency's current thinking on reporting categories for postapproval changes of drugs, other than specified biotechnology and specified synthetic biological products. 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 requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1999

March 25, 1999



---

William K. Hubbard  
Acting Deputy Commissioner for  
Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

*Michael W. Bell*