

Docket No. 99D - 0529

OMB No. 0910 - 0431

SUPPORTING STATEMENT

Guidance for Industry: Changes to an Approved NDA or ANDA

A. Justification

1. Circumstances of Information Collection

This information collection approval request is for a Food and Drug Administration (FDA) guidance for industry entitled "Changes to an Approved NDA or ANDA." The guidance is intended to assist applicants in determining how they should report changes to an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) under section 116 of the Food and Drug Administration Modernization Act (the Modernization Act), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

On November 21, 1997, the President signed the Modernization Act (Pub. L. 105-115) into law. 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 describes requirements and procedures for making and reporting manufacturing changes to approved new drug and abbreviated new drug applications, to new and abbreviated animal drug applications, and to license applications for biological products.

Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act by adding section 506A, which includes the following provisions:

1. A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (sections 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

2. A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when "validating the effects of the change" (section 506A(c)(1) of the act).

3. A major manufacturing change is a manufacturing change