DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–1651] (formerly Docket No. 99D–1651)

Guidance for Industry: Chemistry, Manufacturing, and Control Changes to an Approved New Animal Drug Application or Abbreviated New Animal Drug Application

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#83) entitled ''Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA.'' This guidance is intended to provide recommendations to holders of new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) on how they should report certain changes to such applications, in accordance with the final regulation, 21 CFR 514.8, which was issued in the **Federal Register** of December 13, 2006 (71 FR 74766).

DATES: Comments on agency guidances are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance document 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*.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Jr., Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 1, 1999 (64 FR 53281), FDA published a proposed rule to implement section 506A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356a) for NADAs and ANDAs. In that same issue of the **Federal Register** (64 FR 53393), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA,'' giving interested persons until December 15, 1999, to submit comments. FDA considered all comments received and, where appropriate, incorporated them into the guidance.

This guidance covers recommended reporting categories for various postapproval manufacturing changes and provides recommendations to holders of NADAs and ANADAs on how they should report such changes in accordance with the final regulation, 21 CFR 514.8, issued in the **Federal Register** of December 13, 2006 (71 FR 74766). Recommendations are provided for postapproval changes in: (1) Components and composition, (2) manufacturing sites, (3) manufacturing process, (4) specifications, (5) container closure system, as well as (6) miscellaneous changes and (7) multiple related changes. This guidance does not provide recommendations on the specific information that should be developed by an 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 drug as these factors may relate to the safety or effectiveness of the drug. An applicant should consider all relevant FDA guidance documents for recommendations on the information that should be submitted to support a given change.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the topic. 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 method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in sections II through XI of the guidance have been approved under OMB Control No. 0910–0600.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

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 should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain a copy of the guidance document entitled ''Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA'' from the CVM home page at *http://www.fda.gov/cvm*.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0168]

Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces the availability of draft guidances for industry that describe recommendations on how to design bioequivalence (BE) studies for 200 specific drug products to support abbreviated new drug applications (ANDAs). These draft guidances are being made available