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Publication Date _____

Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0087]

Generic Drug Issues; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting public comments on whether additional regulatory actions should be taken concerning the approval of abbreviated new drug applications (ANDAs). The agency is asking for comments because of recent statutory changes. The agency is not proposing any regulatory changes in this notice. The purpose of this notice is to identify a number of issues that the agency would like interested persons to address and to give interested persons an opportunity to submit comments on possible actions.

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 200857. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Elaine Tseng, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173). Title XI of MMA made changes to section 505(a), (b), and (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 505(a), (b), and (j). In particular, Title XI of MMA made changes to the approval procedures for ANDAs.

FDA is considering what additional regulatory steps, if any, are warranted in light of the statutory changes. The specific portions of the statute for which FDA seeks comment are Title XI of MMA's provisions concerning the 30-month stay of effectiveness period, 180-day exclusivity, and bioavailability and bioequivalence. FDA seeks comments identifying issues contained in the relevant portions of Title XI of MMA, along with any suggestions for how to resolve those issues. FDA will consider these comments in assessing what regulatory actions might be appropriate.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written of electronic comment 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 are to be identified with the docket number found in brackets at the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____
February 27, 2004.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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Dawn P. Hawkins