DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier

Draft Guidance for Industry on Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under PDUFA." This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). Pilot 1 will enable certain applicants to receive early feedback on portions of their applications. Pilot 1 will also evaluate the benefits and costs of providing applicants early feedback.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 45 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER),

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1401 Rockville Pike, Rockville, MD 20852–1448. Send one self addressed adhesive label to assist either office in processing your request. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Jenkins, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3937, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled "Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under PDUFA." In conjunction with the June 2002 reauthorization of PDUFA, FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include two pilot programs to explore the continuous marketing application (CMA) concept. The CMA concept builds on the current practice of interaction between FDA and applicants during drug development and application review and proposes opportunities for improvement.

Under this CMA pilot program, Pilot 1, applicants submitting new drug applications (NDAs) or biological licensing applications (BLAs) for products that have been designated as Fast Track drug or biological products (i.e.,

products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) may be eligible to submit portions of their marketing applications (reviewable units) in advance of the complete marketing application. FDA has agreed to complete reviews of reviewable units within a specified time and to provide early feedback for the presubmissions in the form of discipline review letters.

This draft guidance provides information on how the agency will implement Pilot 1. The draft guidance describes Pilot 1 as an exploratory program that will allow FDA to evaluate the added value, costs, and impact of early review and feedback on parts of applications (reviewable units) in advance of submission of the complete application.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the implementation of the Pilot 1 program for reviewable units of certain Fast Track drug and 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two copies of mailed comments, except that individuals may submit one paper 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 are available for public

examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for a reviewable unit (a predefined portion of an NDA or BLA that may be submitted prior to submission of a complete NDA/BLA) is already covered by the collection of information for NDAs and BLAs (21 CFR 314.50 and 601.2). This notice merely provides applicants an opportunity to submit already required information in advance of the complete NDA or BLA.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection for an application to market a new drug and assigned it OMB control number 0910–0001 (expires March 31, 2005). OMB also approved the information collection for an application to market a biologic product and assigned it OMB control number 0910–0338 (expires March 31, 2005).

IV. Electronic Access

Persons with access to the Internet can obtain the guidance at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Dated: 6/9/03
June 9, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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