John Jenkins, CDER (HFD–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3937, or
Robert A. Yetter, CBER (HFM–25), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a guidance for industry entitled ''Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of 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.

In the **Federal Register** of June 17, 2003 (68 FR 35901), FDA announced the availability of a draft version of this guidance. FDA received a number of comments when it issued the draft version of this guidance. We have considered the comments on the draft guidance carefully and have made some changes to address those comments. Among other things, we have revised the guidance to clarify the eligibility requirements and selection process for Pilot 2 and provide for public availability of additional information during the program.

Under the CMA Pilot 2 program, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to be considered for participation in Pilot 2. Pilot 2 is an exploratory program and FDA will evaluate its impact on the investigational phase of drug development. Under the pilot program, a maximum of one Fast Track product per review division in CDER and CBER will be selected to participate. This guidance provides information regarding the selection of applications for Pilot 2, the formation of agreements between FDA and applicants on the investigational new drug application communication process, and other procedural aspects of Pilot 2. See **DATES** for when FDA will begin accepting applications for participation in Pilot 2.

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collection(s) of information in this guidance was approved under OMB control number 0910–0518, and will expire on March, 31, 2004. In the notice announcing the availability of the draft version of this guidance (68 FR 35901), FDA published a notice of the proposed collection of information related to the draft guidance. The **Federal Register** notice also requested comments on the burden estimated for the guidance. In the **Federal Register** of September 9, 2003 (68 FR 53174), the agency announced that it was submitting the collection of information to OMB for review and clearance under the PRA. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The time required to complete this information collection is estimated to average 80 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this 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 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 guidance at any time. Two copies of mailed 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 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. 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: September 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25305 Filed 10–1–03; 4:09 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0228]

Guidance for Industry on Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act of 1992

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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 early feedback to applicants.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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 the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your requests. Submit written comments on the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: John Jenkins, CDER (HFD–020), Food

and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–3937, or
Robert A. Yetter, CBER (HFM–25), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a 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.

In the **Federal Register** of June 17, 2003 (68 FR 35903), FDA announced the availability of a draft version of this guidance. FDA received a number of comments on the draft guidance. We have considered the comments carefully and have made some changes to address those comments. Among other things, we have revised the guidance to further describe the selection of marketing applications for inclusion in Pilot 1, clarify the content and submission process for reviewable units, and provide for public availability of additional information during the program.

Under the CMA pilot program, Pilot 1, applicants submitting new drug applications or biological licensing applications 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 those presubmissions in the form of discipline review letters.

This guidance provides information on how the agency will implement Pilot 1. As described in the guidance, Pilot 1 is 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 level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 guidance at any time. Two copies of mailed 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 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. 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: September 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25306 Filed 10–1–03; 4:09 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

Proposed Project: HRSA AIDS Education and Training Centers Evaluation Activities—NEW

The AIDS Education and Training Centers (AETC) Program, under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, supports a network of regional and cross-cutting national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of a national evaluation effort of AETC activities, one questionnaire and several record-keeping forms have been developed to capture information on AETC activities. The first form is the Participant Information Form and asks trainees for information on the individual's profession, type of clinical practice, and patient population. Recordkeeping forms include (1) the Program Record which records information such as topic, training time, number of people reached, and format per training activity, (2) the Clinical Consultation Form which collects information on consults with a provider regarding a specific patient, (3) the Group Clinical Consultation Form which records information on the nature of the cases discussed and the session format during a site visit, and (4) the Agency Technical Assistance Form which collects information on activities to improve non-clinical aspects of care (*e.g.*, medical records, resource allocation). The information on the recordkeeping forms comprises a core data set that will be submitted to the HIV/AIDS Bureau (HAB) data contractor three times per year.

Each center will be required to report aggregate data from these forms on their activities to HRSA/HAB. This data collection will provide information on the number of training, consultation, and technical assistance activities by center, the number of health care providers receiving professional training or consultation, the time and effort expended on different types of training and consultation activities, the populations served by the AETC trainees, and the increase in capacity achieved through training and technical assistance activities. Collection of this information will allow HRSA/HAB to provide information on training activities, types of education and