reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Data submission is voluntary and is self reported by the health care provider.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 03–15120 Filed 6–16–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Draft Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.'' This guidance discusses how the agency will implement a pilot program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of the development of certain Fast Track drug and biological products. Applicants are being asked to apply to participate in the Pilot 2 program.

DATES: Submit written comments on the draft guidance by August 1, 2003. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collection of information by August 15, 2003.

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 request. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidances.

Submit written comments on the draft guidance and on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the collection of information to *http://www.fda.gov/dockets/ecomments*.

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 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.'' In conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (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 2, 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 participate in Pilot 2. Pilot 2 is an exploratory program that will allow FDA to evaluate the impact of frequent scientific feedback and interactions with applicants during the investigational new drug application (IND) phase. 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 participant applications for Pilot 2, the formation of agreements between FDA and applicants on the IND communication process, and other procedural aspects of Pilot 2. The FDA will begin accepting applications for participation in Pilot 2 on October 1, 2003.

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 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 draft guidance and the information collection. 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 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

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be

collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques and other forms of information technology, when appropriate.

Title: Draft guidance for industry ''Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.

Description: FDA is issuing a draft guidance on the implementation of a pilot program to provide selected applicants of Fast Track drugs or biologics with frequent scientific feedback and interactions during the IND development phase. The draft guidance describes the criteria, procedures, and the application process to participate in Pilot 2.

The draft guidance describes one collection of information: Applicants who would like to participate in Pilot 2 must submit an application (Pilot 2 application) containing certain information outlined in the draft guidance. The purpose of the Pilot 2 application is for the applicants to describe how their designated Fast Track product would benefit from enhanced communications between the FDA and the applicant during the product development process.

Section 312.23 (21 CFR 312.23) of the FDA regulations states that information provided to the agency as part of an IND must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs. FDA Form 1571 has a valid OMB control number: OMB Control No. 0910–0014, which expires January 31, 2006.

In the draft guidance document, CDER and CBER ask that a Pilot 2 application be submitted as an amendment to the application for the underlying product under the requirements of § 312.23; therefore, Pilot 2 applications should be submitted to the agency in triplicate with Form FDA 1571. The agency recommends that a Pilot 2 application be submitted in this manner for two reasons: (1) To ensure that each Pilot 2 application is kept in the administrative file with the entire underlying application and (2) to ensure that pertinent information about the Pilot 2 application is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the agency to monitor progress on activities.

Under the draft guidance, the agency asks applicants to include the following information in the Pilot 2 application:

- Cover letter prominently labeled ''Pilot 2 application;''
- IND number;
- Date of Fast Track designation;
- Date of the end-of-phase 1 meeting, or equivalent meeting, and summary of the outcome;
- A timeline of milestones from the drug or biological product development program, including projected date of new drug application/biologic licensing applications submission;
- Overview of the proposed product development program for a specified disease and indication(s), providing information about each of the review disciplines (e.g., continuous marketing applications, pharmacology/toxicology, clinical, clinical pharmacology and biopharmaceutics);
- Rationale for interest in participating in Pilot 2, specifying the ways in which development of the subject drug or biological product would be improved by frequent scientific feedback and interactions with FDA and the potential for such communication to benefit public health by improving the efficiency of the product development program; and
- Draft agreement for proposed feedback and interactions with FDA.

This information will be used by the agency to determine which Fast Track products are eligible for participation in Pilot 2.

Description of Respondents: An applicant for a drug or biological product that has been designated as Fast Track under section 112 of the FDA Modernization Act (21 U.S.C. 356).

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden[1] for the submission of a Pilot 2 application under the guidance. Participation in this pilot program will be voluntary.

Based on the number of approvals for Fast Track designations and data collected from the review divisions and offices within CDER and CBER, FDA estimates that in fiscal year (FY) 2002, 109 drug product applications and 46 biological products had Fast Track designation. FDA anticipates that approximately 85 drug product applicants (respondents) and approximately 29 biological product applicants (respondents) will submit at least one Pilot 2 application. Based on information collected from offices within CDER and CBER, the agency further anticipates that the total responses, i.e., the total number of applications received for Pilot 2, will be 90 for drug products and 35 for biological products. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted in a Pilot 2 application in accordance with the draft guidance, is estimated to be approximately 80 hours. Based on FDA's experience, we expect it will take respondents this amount of time to obtain and draft the information to be submitted with a Pilot 2 application. Therefore, the agency estimates that applicants will use approximately 10,000 hours to complete the Pilot 2 applications.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Pilot 2 application	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
CDER	85	1.06	90	80	7,200
CBER	29	1.20	35	80	2,800
Total					10,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

[1] The burden estimate is for the application period because this is a pilot program and limited in duration.

IV. Electronic Access

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

Dated: June 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15168 Filed 6–12–03; 11:36 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0228]

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 August 1, 2003. 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), 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: June 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15167 Filed 6–16–03; 11:36 am]

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