SUPPORTING STATEMENT

Guidance for Industry - Continuous Marketing Applications: Pilot 2 — Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA
OMB Control Number 0910-0518
Expires September 30, 2010

A. Justification

1. Circumstances of Information Collection

FDA is requesting OMB approval under the PRA (44 U.S.C. 3507) for the reporting and recordkeeping requirements contained in the 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 asked to apply to participate in the Pilot 2 program.

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 the CMA pilot program, Pilot 2, certain drug



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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 the program. Pilot 2 is an exploratory program that allows 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 is 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. FDA began accepting applications for participation in Pilot 2 on October 1, 2003.

The 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 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 FDA and the applicant during the product development process.

FDA's regulation at 21 CFR 312.23 (21 CFR 312.23) 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. 21 CFR part 312 and FDA Form 1571 have a valid OMB control number: OMB Control No. 0910-0014.

In the guidance document, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (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 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 NDA/BLA submissions;
- Overview of the proposed product development program for a specified disease and indication(s), providing information about each of the review disciplines (e.g., chemistry/ manufacturing/ controls, 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 is used by the agency to determine which Fast Track products are eligible for participation in Pilot 2. Participation in this pilot program is voluntary.

2. Purpose and Use of Information

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 the 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 the program. 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.

3. Use of Improved Information Technology

The following guidances for industry are among those that

have been developed to improve the use of information technology in the submission of marketing applications for human drugs and related reports:

- "Providing Regulatory Submissions in Electronic Format--NDAs" (January 28, 1999). This guidance provides information on how to submit a complete archival copy of an NDA in electronic format and applies to the submission of original NDAs as well as to the submission of supplements and amendments to NDAs.
- "Providing Regulatory Submissions in Electronic Format--General Considerations" (January 28, 1999). This guidance includes a description of the types of electronic file formats that the agency is able to accept to process, review, and archive electronic documents. The guidance also states that documents submitted in electronic format should enable the user to: (1) Easily view a clear and legible copy of the information; (2) print each document page by page while maintaining fonts, special orientations, table formats, and page numbers; and (3) copy text and images electronically into common word processing documents.
- “Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format” (November 12, 1999). This guidance provides information to assist applicants in submitting documents in electronic format

for review and archive purposes as part of a BLA, product license application (PLA), or establishment license application (ELA).

- "Providing Regulatory Submissions in Electronic Format-—Prescription Drug Advertising and Promotional Labeling" (January 31, 2001). This draft guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products.
- "Providing Regulatory Submissions in Electronic Format-—ANDAs" (June 27, 2002). This guidance discusses issues related to the electronic submission of ANDAs and supplements and amendments to those applications.
- "Providing Regulatory Submissions in Electronic Format-—Annual reports for NDAs and ANDAs" (August 2003). This guidance discusses issues related to the electronic submission of annual reports for NDAs and ANDAs.
- "Providing Regulatory Submissions in Electronic Format-—Postmarketing Periodic Adverse Drug Experience Reports" (June 2003). This guidance discusses general issues related the electronic submission of postmarketing periodic adverse drug experience reports for NDAs, ANDAs, and BLAs.
- "Providing Regulatory Submissions in Electronic Format-—Human Pharmaceutical Product Applications and Related Submissions" (August, 2003). This draft guidance discusses issues related to the electronic submission of ANDAs, BLAs, INDs, NDAs, master

files, advertising material, and promotional material.

• "Providing Regulatory Submissions in Electronic Format-—General Considerations" (October 2003). This draft guidance discusses general issues common to all types of electronic regulatory submissions.

• "Providing Regulatory Submissions in Electronic Format-—Content of Labeling" (February 2004). This draft guidance discusses issues related to the submission of the content of labeling in electronic format for marketing applications for human drug and biological products.

These guidance documents and others are available at FDA's web site http://www.fda.gov/cder/guidance/index.htm.

4. Efforts to Identify Duplication

The information collection requested under the guidance does not duplicate any other information collection.

5. Involvement of Small Entities

Although new drug development is typically an activity completed by large multinational drug firms, the information collection requested under the guidance applies to small as well as large companies. Under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small

businesses in complying with regulatory requirements.

6. Consequences If Information Collected Less Frequently

As discussed, the information as requested is necessary for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of development of certain Fast Track drug and biological products.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

Inconsistency with the guidelines concerning the number of copies submitted is approved by OMB under OMB Control Number 0910-0014.

8. Consultation Outside the Agency

In the Federal Register of July 24, 2006 (71 FR 41819), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. No comments were received that pertained to the information collection estimates.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under this guidance.

10. Assurance of Confidentiality

Confidentiality of the information submitted under this guidance is protected under 21 CFR 312.130 and 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

Based on the number of Pilot 2 applications submitted to CDER and CBER during fiscal year 2004 and 2005, we estimate that the number of applications received annually for Pilot 2 is 7 for products regulated by CDER and 1 for products regulated by CBER. FDA anticipates that approximately 7 applicants (respondents) will submit these Pilot 2 applications annually to CDER and approximately 1 applicant (respondent) will submit these Pilot 2 applications annually to CBER. 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 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 use approximately 640 hours annually to submit the Pilot 2 applications.

Table 1.--Estimated Annual Reporting Burden

| Pilot 2 Application | Number of Respondents | Number of Responses per Respondent | Total Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| CDER | 7 | 1 | 7 | 80 | 560 |
| CBER | 1 | 1 | 1 | 80 | 80 |
| Total | | | | | 640 |

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

13. Estimates of Annualized Cost Burden to Respondents

FDA has estimated an average industry wage rate of $50.00 per hour for preparing and submitting the information collection requirements under OMB Control Number 0910-0014. Using the averaged wage rate of $50.00 per hour, and multiplied times the total hour burden estimated above, the total cost burden to respondents is $ 32,000 (640 x $50).

14. Estimates of Annualized Cost Burden to the Government

FDA estimates that review of the Pilot 2 applications will take approximately 320 hours (8 applications x 40 hours per application). Using the averaged cost of $50 per hour for each reviewer, the cost to FDA is estimated to be $16,000.

15. Changes In Burden

The changes in burden result from more recent data on the

number of Pilot 2 application submissions, which is lower than original estimates 3 years ago.

16. Time Schedule, Publication, and Analysis Plans

There are no publications.

17. Displaying of OMB Expiration Date

The agency is not seeking to display the expiration date for OMB approval of the information collection.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.