

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Title: Draft guidance for industry “Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.

Description: FDA is issuing a draft guidance on the implementation of a pilot program to provide selected applicants of Fast Track drugs or biologics with frequent scientific feedback and interactions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 The draft guidance describes the criteria, procedures, and the application process to participate in Pilot 2.

The draft guidance describes one collection of information: Applicants who would like to participate in Pilot 2 must submit an application (Pilot 2 application) containing certain information outlined in the draft guidance.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In the draft guidance document, CDER and CBER ask that a Pilot 2 application be submitted as an amendment to the application for the underlying product under the requirements of §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Under the draft guidance, the agency asks applicants to include the following information in the Pilot 2 application: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 burden¹ 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 BURDEN¹

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.