

(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 the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (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. FDA will begin 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 the FDA and the applicant during the product development process.

FDA's regulation at § 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. Both 21 CFR part 312 and FDA Form 1571 have a valid OMB control number (OMB control number 0910-0014), which expires January 31, 2006.

In the 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 data bases. 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/biologic license application 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 will be used by the agency to determine which Fast Track products are eligible for participation in pilot 2. 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 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 submitting 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 will use approximately 10,000 hours to complete the pilot 2 applications.

On September 29, 2003, this guidance was approved on an emergency basis, which expires on March 30, 2004. This notice of request is to receive approval in the normal PRA process.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Pilot 2 Application	No. of Respondents	No. of Responses per Respondent	Total 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 collection of information.