

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0526]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by [*insert date 30 days after date of publication in the **Federal Register***].

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review—(OMB Control Number 0910–0389)—Extension**

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under FDAMA section 112(b), FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the act. The guidance discusses collections of information that are specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving the following collection of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

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Under section 506(a)(1) of the act, an applicant who seeks fast track designation is required to submit a request to the agency showing that the product may do the following: (1) Is intended for a serious or life-threatening condition and (2) the product has the potential to address an unmet medical need. Mostly, the agency expects that information to support a designation request will have been gathered under existing provisions of the act, the PHS Act, or implementing regulations. If such information has already been submitted to the agency, the information may be summarized in the fast track designation request. The guidance recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the agency makes a fast track designation, a sponsor or applicant may submit a premeeting package, which may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the agency expects that most sponsors or applicants will have already gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations. These may include

descriptions of clinical safety and efficacy trials not conducted under an investigational new drug application (IND) (i.e., foreign studies), and information to support a request for accelerated approval. If such information has already been submitted to FDA the information may be summarized in the premeeting package. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Under section 506(c) of the act, a sponsor must submit sufficient clinical data for the agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that is not required under section 506(c) of the act or any other provision of the act. All forms referred to in the guidance have a current OMB approval: FDA Forms 1571 (OMB control number 0910–0014, expires January 31, 2006); 356h (OMB control number 0910–0338, expires August 31, 2005); and 3397 (OMB control number 0910–0297, expires December 31, 2006).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the act. The agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will be approximately 56. To obtain this estimate, FDA averaged the number of requests for fast track designation received by CBER and CDER in the 3-year period from 2001 to 2003. For these 3 years, CBER and CDER together received a yearly average of 67 requests from 56 respondents. The rate of submissions is not expected

to change significantly in the next few years. FDA estimates that the number of hours needed to prepare a request for fast track designation may range between 40 and 80 hours per request, depending on the complexity of each request, with an average of 60 hours per request, as indicated in table 1 of this document.

Not all requests for fast track designation may meet the statutory standard. Of the average 67 requests made per year, the agency granted 47 requests for fast track designation. For each of the 47 granted requests, FDA estimates that a premeeting package was submitted to the agency. FDA estimates that the preparation hours may generally range between 80 and 120 hours, with an average of 100 hours per package, as indicated in table 1 of this document.

In the **Federal Register** of December 13, 2004 (69 FR 72202), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received but was not related to the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Reporting Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Designation Request	56	1.20	67	60	4,020
Premeeting Packages	47	1.00	47	100	4,700
Total					8,720

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 31, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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