

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

21 CFR 314.81(b)(2)(ii)(b)	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response (in hours)	Total hours
The submission of a copy of that portion of each annual report containing authorized generic drug information ....	60	6.7	400	3/60	20
Total .....	.....	.....	.....	.....	520

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

Dated: April 7, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-8820 Filed 4-12-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0157]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information concerning requests by sponsors of investigational new drugs and applicants for new drug approvals or biologics licenses for fast track designation as provided in the guidance for industry on fast track drug development programs.

**DATES:** Submit either electronic or written comments on the collection of information by June 13, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under 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. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 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, including each proposed extension of an existing 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 these topics: (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 of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

#### 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) (Pub. L. 105-115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C 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 section 112(b) of FDAMA, FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the FD&C Act. The guidance discusses collections of information that are specified under section 506 of the FD&C Act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving 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.

Under section 506(a)(1) of the FD&C Act, an applicant who seeks fast track designation is required to submit a request to the Agency showing that the product: (1) Is intended for a serious or life-threatening condition and (2) 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 FD&C Act, the PHS Act, or the 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 gathered such information to meet existing requirements under the FD&C 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 FD&C 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 are not required under section 506(c) of the FD&C Act or any other

provision of the FD&C Act. All forms referred to in the guidance have a current OMB approval: FDA Forms 1571 (OMB control number 0910-0014); 356h (OMB control number 0910-0338); and 3397 (OMB control number 0910-0297).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the FD&C Act. The Agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research is approximately 97, and the number of requests received is approximately 118 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request.

Not all requests for fast track designation may meet the statutory standard. Of the requests for fast track designation made per year, the Agency granted 77 from 64 respondents, and for each of these granted requests a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package.

FDA estimates the burden of this collection of information as follows:

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

Reporting activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Designation Request .....	97	1.22	118	60	7,080
Premeeting Packages .....	64	1.20	77	100	7,700
Total .....					14,780

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

Dated: April 4, 2011.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0627]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval To Market a New Drug**

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

**ACTION:** Notice.

**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 May 13, 2011.

**ADDRESSES:** 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: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0001. Also include the FDA docket number found