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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 01N-0458]

Agency Information Collection Activities; Submission for OMB Review; 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 that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

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

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JennaLynn P. Capezzuto, Office of Information Resources Management (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.

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Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review (OMB Control No. 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 demonstrates 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 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 collections 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 act, an applicant who seeks fast track designation is required to submit a request to the agency showing that the product meets the statutory standard for designation, i.e., that: (1) The product 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 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. 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 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. The discussion of such information in a premeeting package may be summarized if it has already been previously submitted to FDA under an OMB approved collection of information. 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) of the act 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 No. 0910–0014, expires September 30, 2002); 356h (OMB Control No. 0910–0338, expires March 31, 2003); and 3397 (OMB Control No. 0910–0297, expires February 29, 2004).

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 45. To obtain this estimate, FDA averaged the number of requests for fast track designation received by CBER and CDER in the 3-year period of 1998 to 2000. For these 3 years, CBER and CDER together received a yearly average of 53 requests from 45 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 53 requests made per year, the agency granted 33 requests for fast track designation. For each of the 33 granted requests, FDA estimates that a premeeting package was submitted to the agency. FDA estimates that a premeeting package needs more preparation time than needed for a designation request because the issues may be more complex and the data may need to be more developed. 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. The hour burden estimates contained in table 1 of this document are for information collections requests in the guidance only and do not include burden estimates for statutory requirements specifically mandated by the act, the PHS Act, or implementing regulations. FDA estimates the burden of this collection of information as follows:

In the **Federal Register** of October 23, 2001 (66 FR 53612), FDA published a 60-day notice requesting public comment on the information collection provisions (the October 2001 notice). One letter of comment was received in response to the 60-day notice on the information collection.

The comment declared, without any explanation or supporting information, that the proposed collection of information was unnecessary. The comment also attempted to reserve judgment as to whether our estimated information collection burden was accurate. The comment seemed to object to fast track drug development programs and stated in part that “for our Congress to even think about letting it happen is playing games with the existing laws.”

FDA disagrees with the comment. Section 506 of the act requires sponsors to submit sufficient clinical data for FDA to determine, after preliminary evaluation, whether a fast track product may be effective. To obtain that clinical data as described in the guidance document, FDA must have an approved collection of information. Failure to obtain OMB approval for the proposed collection of information would undermine the guidance document’s value (because FDA might not receive information that would help the review or receive unnecessary or confusing information) and ultimately undermine the efficiency of the review under a fast track drug development program.

Additionally, the October 2001 notice provided sufficient information and opportunity for public comment on the information collection burden estimates given in the notice. The comment received did not provide any figures or explanations that would cause us to change our burden estimates, so FDA has no reason to revise the collection burden estimates.

As for the comment’s remarks regarding fast track drug development programs and Congress, such matters are outside the scope of this notice. We do, however, regard the statute as providing sufficient safeguards to prevent unsafe or ineffective drugs from reaching the public.

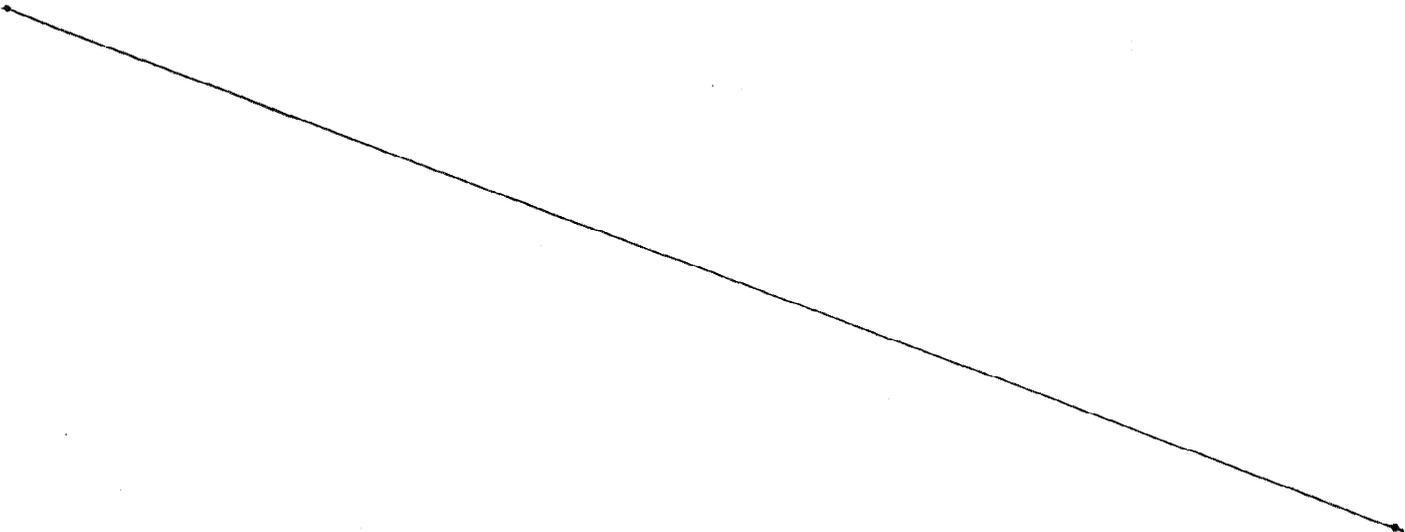
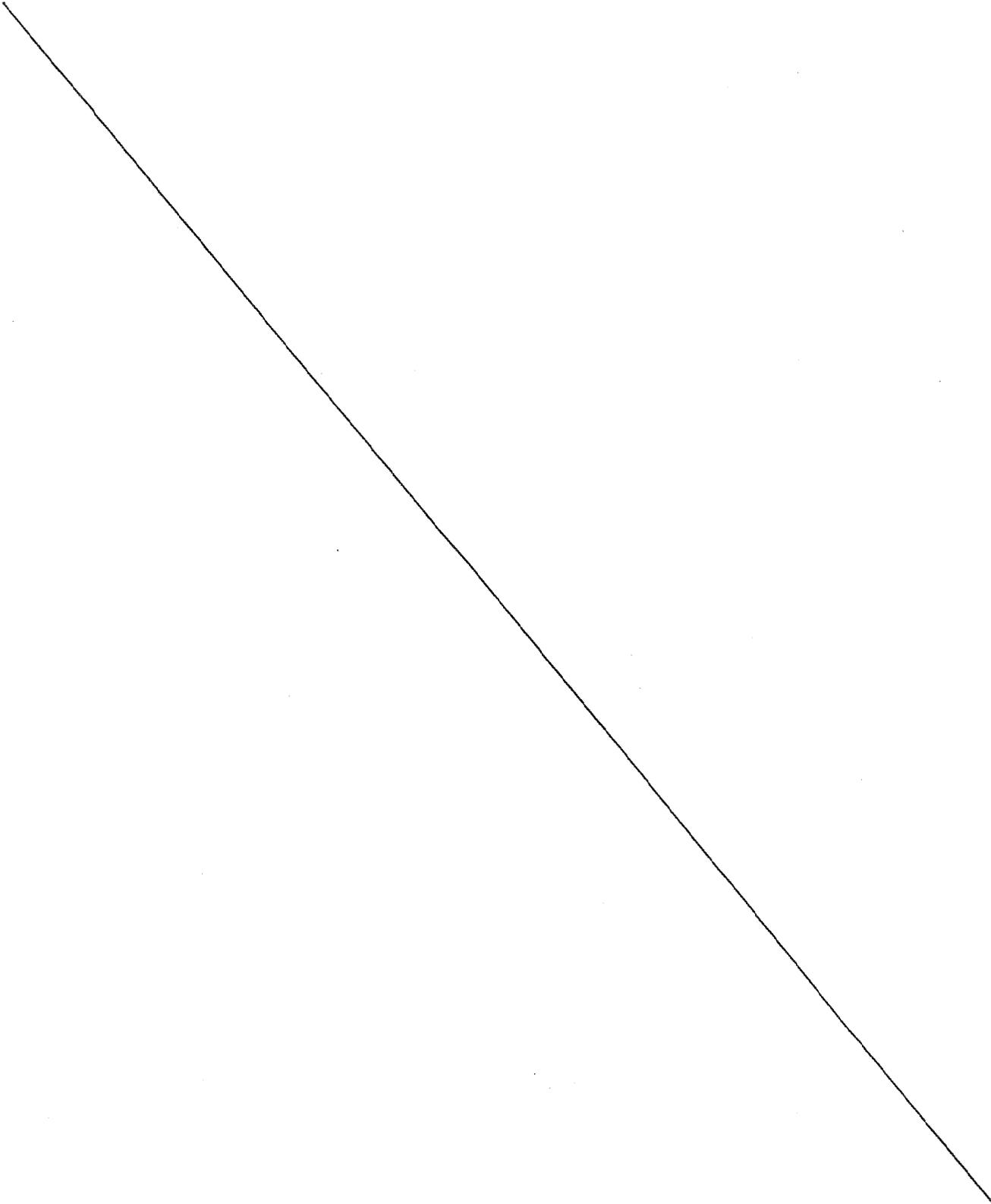


TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

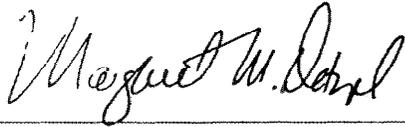
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation request	45	1.18	53	60	3,180
Premeeting packages	33	1.00	33	100	3,300
Total					6,480

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



Dated: 3-19-02

March 19, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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