TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
312.160(a)	3,400	7.35	25,000	30 min	1,700
312.160(c)	320	1	320	0.5	160
Total Biologic Recordkeeping Hours					655,855
Total Biologics Burden Hours					5,665,452.5
Total Human Drugs Burden Hours					11,575,113
Total Combined Burdens					17,240,565.5

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

Dated: April 29, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11310 Filed 05–05–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0811]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: Designation, Development, and Application Review for Products in Fast-Track Drug Development Programs

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 (the PRA).

DATES: Submit written comments on the collection of information by June 7, 1999.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn 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.

Guidance for Industry: Designation, Development, and Application Review for Products in Fast-Track Drug Development Programs

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356) and 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 meet an unmet medical need. The issuance of the guidance will be under section 112(b) of FDAMA, which requires the agency to issue guidance regarding fast-track policies and procedures within 1 year of the date of enactment of FDAMA, November 21, 1997. The guidance will discuss collections of information that are expressly specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. For example, under section 506 of the act, an applicant who seeks fast-track designation must submit a request to FDA. Some of the support for such a request may be required under regulations, such as parts 312, 314, and 601 (21 CFR parts 312, 314, and 601), which specify the types and format of information and data that should be submitted to FDA for evaluation of the safety and effectiveness of investigational new drug applications (IND's) (part 312), new drug applications (part 314), or biological license applications (part 601). The guidance will describe three general areas involving collection of information: Designation requests, premeeting packages, and requests to submit portions of an application. Of these, designation requests, and premeeting packages in support of obtaining a fast-track program benefit will provide for additional collections of information not provided 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, in some cases, may be incorporated by referring to them rather than by resubmission. In some instances, a summary of data and information may be submitted in support of fast-track designation or fast-track program benefits. Therefore, FDA anticipates that the PRA reporting burden under the guidance will be minimal.

Under section 506(a)(1) of the act, an applicant who seeks fast-track designation is required to submit a request to the agency. In order to receive a fast-track designation, the requester must establish 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. In most cases, 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 regulation. Such information, if already submitted to the agency, may be summarized in a fast-track designation request.

The guidance will also recommend 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 meet an unmet medical need where 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 to support 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, such as descriptions of clinical safety and efficacy trials not conducted under an IND (i.e., foreign studies), and information to support a request for accelerated approval. If information has been previously submitted to FDA under an OMB approved collection of information, the discussion of such information in a fast-track premeeting package may be summarized. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Section 506(c) of the act requires a collection of information before an applicant may be permitted to submit to FDA portions of an application for review. Under this provision of the fast-track statute, a sponsor must submit clinical data sufficient 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 will 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 that will be referred to in the guidance have valid OMB control numbers. These forms include: FDA Form 1571 (OMB Control No. 0910–0104, expires December 31, 1999); FDA Form 356h (OMB Control No. 0910–0338, expires April 30, 2000); and FDA Form 3397 (OMB Control No. 0910–0297, expires April 30, 2001). Respondents to this information collection are sponsors and applicants that seek fast-track designation under section 506 of the act. The agency estimates that the aggregate 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 60. To obtain this estimate, FDA extrapolated from the number of requests for fast-track designation actually received by CBER and CDER in a 6-month period since November 21, 1997, the date of enactment of FDAMA. Within this time period, CBER received 9 requests, and CDER received 20 requests. FDA estimates that the number of hours needed to prepare a request for fast-track designation may generally 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. The agency estimates that approximately 90 percent of all annual requests, approximately 54 respondents, for fast-track designation would be granted. Of those respondents who receive fast-track designation for a product, FDA expects that all will submit a premeeting package and that a premeeting package would generally need 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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request	60	1	60	60	3,600
Premeeting Packages	54	1	54	100	5,400
Totals	114		114		9,000

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

Dated: April 29, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–11311 Filed 5–5–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1170]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-methyl-4,6-bis-[(octylthio)]methyl] phenol as a stabilizer for repeat use rubber articles.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4660) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., P.O. Box 2005, Tarrytown, NY 10591–9005. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010)to provide for the safe use of 2-methyl-4,6-bis-[(octylthio)]methyl] phenol as a stabilizer for repeat use rubber articles.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.