Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 21, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–1860 Filed 1–26–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0811]

Agency Information Collection Activities: Proposed Collection; 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 an opportunity for public comment on the proposed collection of 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 submissions by sponsors of investigational new drugs and applicants for new drug approvals or biological licenses that request fast-track designation and the guidance for industry on fast-track drug development programs.

DATES: Submit written comments on the collection of information by March 29, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: 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: 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 of the 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 listed as follows.

With respect to the following collection of information, FDA invites comment on: (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: Designation, Development, and Application Review for Products in Fast-track Drug Development Programs (OMB Control Number 0910–0389)—Extension

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, may, in some cases, 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) 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) 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: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1797 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0143]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors with Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors with Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of October 21, 1998 (63 FR 56192), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0388. The approval expires on April 30, 1999.

Dated: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1795 Filed 1–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0721]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Premarket Approval of Medical Devices

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 February 26, 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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance. In the **Federal Register** of October 6, 1998 (63 FR 53675), the agency requested comments on the proposed collection of information. No comments were received.

Due to a clerical error, the title of the information collection that appeared in the **Federal Register** of October 6, 1998, was incorrect. The correct title follows.

I. Premarket Approval of Medical Devices—21 CFR Part 814 and FDAMA Sections 201, 202, 205, 207, 208, 209 (OMB Control Number 0910–0231—Extension)

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth requirements for premarket approval of certain medical devices. Under section 515 of the act, an application must contain several pieces of information, including: Full reports of all information concerning investigations showing whether the device is safe and effective; a statement of components; a full description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device; and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a premarket approval application (PMA) for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA. The purpose of these regulations is to establish an efficient and thorough procedure for FDA's review of PMA's for class III (premarket approval) medical devices. The regulations will facilitate the approval of PMA's for devices that have been shown to be safe and effective and otherwise meet the statutory criteria for approval. The regulations will also ensure the disapproval of PMA's for devices that have not been shown to be safe and effective and that do not otherwise meet the statutory criteria for approval.

Under § 814.15, an applicant may submit in support of a PMA studies from research conducted outside the United States, but an applicant must explain in detail any differences between standards used in a study to support the PMA's and those standards found in the Declaration of Helsinki. Section 814.20 provides a list of information required in the PMA, including: A summary of information in the application, a complete description of the device, technical and scientific information, and copies of proposed labeling. Section 814.37 provides requirements for an applicant who seeks to amend a pending PMA. Section 814.82 sets forth postapproval requirements FDA may propose, including periodic reporting on safety effectiveness, and reliability, and display in the labeling and advertising of certain warnings. Other potential postapproval requirements include the maintenance of records to trace patients and the organizing and indexing of records into identifiable files to enable FDA to determine whether there is reasonable assurance of the device's continued safety and effectiveness. Section 814.84 specifies the contents of periodic reports.