Flores v. *Reno* settlement agreement, No. CV85–4544–RJK (C.D. Cal. 1997). ORR considers the suitability of a sponsor based on the sponsor's ability and agreement to provide for the physical, mental and financial well-being of an unaccompanied minor and the sponsor's assurance to appear before immigration courts. To ensure the safety of the children, sponsors must undergo a background check. Suitable sponsors may be parents, close relatives, friends or entities concerned with the child's welfare. In this Notice, ACF announces that it proposes to employ the use of several information collections for recording: (1) The Sponsor's Agreement to Conditions of Release, which collects the sponsor's affirmation to the terms of the release; (2) the Verification of Release, which collects the children's affirmation to the terms of their release; (3) the Family Reunification Packet, which collects information related to the sponsor's ability to proved for the physical, mental and financial well-being of the child(ren); and (4) the Authorization for Release of Information, which collects information to be utilized for a background check.

Respondents: Potential sponsors of unaccompanied alien children and unaccompanied alien children in Federal custody.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sponsor's Agreement	3,000	1	.166666	500
Verification of Release	3,000	1	.166666	500
Family Reunification Packet	3,000	20	.05	3,000
Authorization for Release of Information	3,000	12	.05	1,800
Estimated Total Annual Burden Hours				5,800

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and 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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov.* 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: December 6, 2004.

Robert Sargis,

Reports Clearance.

[FR Doc. 04–27243 Filed 12–10–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0526]

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 for fast track designation by sponsors of investigational new drugs (INDs) and applicants for new drug approvals or biological licenses as provided in the guidance for industry on fast track drug development programs.

DATES: Submit written or electronic comments on the collection of information by February 11, 2005.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments.* 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: JonnaLynn P. Capezzuto, Office of Management Programs (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 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 comment 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) (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 the potential to address an unmet medical need. Under 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 collections of information: (1) Fast track designation requests, (2) pre-meeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and pre-meeting 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 pre-meeting 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 IND (i.e., foreign studies), and information to support a request for accelerated approval. The discussion of such information in a pre-meeting 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 solely attributed 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) 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 September 30, 2002); 356h (OMB control number 0910–0338, expires March 31, 2003); and 3397 (OMB control number 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 pre-meeting package was submitted to the agency. FDA estimates that a pre-meeting 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 for a pre-meeting package may range between 80 and 120 hours per package, with an average of 100 hours per package, as indicated in table 1 of this document.

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	45	1.18	53	60	3,180
Pre-meeting 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: December 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–27198 Filed 12–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project: State-by-State Self Assessment of Trauma Care Systems—Reinstatement (OMB No. 0915–0259)

HRSA proposes to collect data from the 56 States and Territories on their current trauma care systems to assess progress since the initial survey in fiscal year 2002. This information will be used to establish a national strategy to assist in future grant opportunities to the States to improve or enhance their basic systems infrastructure in trauma care delivery, as well as their collection and usage of quality trauma data.

HRSA will be collaborating with partners from within HRSA's Healthcare Systems Bureau, Division of Healthcare Preparedness (DHP), Bioterrorism Hospital Preparedness Program; HRSA's Office of Rural Health Policy; and HRSA's Maternal and Child Health Bureau. In addition, HRSA will collaborate with the Office of Public Health Emergency Preparedness; the Agency for Healthcare Research and Quality; the Centers for Disease Control and Prevention's Center for Injury Prevention and Control; the National Highway Traffic and Safety Administration's Emergency Medical Services (EMS) Division; and affiliated professional organizations through the DHP Trauma Program's National Trauma-EMS Stakeholder Group. HRSA has included national performance measures for Trauma/EMS for this project in accordance with the requirements of the ''Government Performance and Results Act (GPRA) of 1993'' (Public Law 103–62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance.

The estimated response burden is as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Self Assessment questionnaire	56	1	10	560
Total	56			560

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 29, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–27199 Filed 12–10–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Loan Repayment Program for Repayment of Health Professions Educational Loans Announcement Type: Initial CFDA Number: 93.164

Dates: Please see Section IV, 3.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2005 includes $12,974,300 for the Indian Health Service (IHS) Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs.

This program announcement is subject to the appropriation of funds.