Application Consideration: The Commissioner's funding decision is based on an analysis of the application by the review panel, panel review scores and recommendations; an analysis by ANA staff; review of previous ANA grantee's past performance; comments from State and Federal agencies having contract and grant performance related information; and other interested parties. The Commissioner makes grant awards consistent with the purpose of the Native American Programs Act (NAPA), all relevant statutory and regulatory requirements, this program announcement, and the availability of appropriated funds. The Commissioner reserves the right to award more, or less, than the funds described or under such circumstances as may be deemed to be in the best interest of the Federal government. Applicants may be required to reduce the scope of projects based on the amount of approved award.

Federal. Since ACF will be using non-Federal reviewers in the process, applicants have the option of omitting from the application copies (not the original) of specific salary rates or amounts for individuals specified in the application budget and Social Security numbers, if otherwise required for individuals. The copies may include summary salary information.

Approved but Unfunded Applications. Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

3. Anticipated Announcement and Award Dates

Approximately 120 days after the application due date, the successful applicants will be notified by mail through the issuance of a Financial Assistance Award document which will set forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and sent to the applicant's Authorizing Official. Applications not funded in this competition will be notified in writing.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR part 92 (governmental); 45 CFR part 1336; and, Native American Programs Act of 1974–42 U.S.C. 2991 *et seq.*

Direct Federal grants, subaward funds, or contracts under this Program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the prohibition of Federal funds for inherently religious activities can be found on the HHS Web site at: *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

3. Reporting Requirements

Program Progress Reports: Quarterly
Financial Reports: Quarterly

Special Reporting Requirements: An original and one copy of each performance report and financial status report must be submitted to the Grants Officer. Failure to submit these reports when required will mean the grantee is non-compliant with the terms and conditions of the grant award and subject to administrative action or termination. Program progress reports are submitted 30 days after each quarter (3-month intervals) of the budget period. The final program progress report, due 90 days after the project period end date, shall cover grantee performance during the entire project period. All grantees shall use the SF 269 (Long Form) to report the status of funds. Financial Status Reports are submitted 30 days after each quarter (3-month intervals) of the budget period. The final SF 269 report shall be due 90 days after the end of the project period.

VII. Agency Contacts

Program Office Contact

ANA Applicant Help Desk, Aerospace Center, 8th Floor West, 370 L'Enfant Promenade SW., Washington, DC 20047, Phone: 877–922–9262, E-mail: *ana@acf.hhs.gov.*

Grants Management Office Contact

Tim Chappelle, Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade SW., Aerospace Building 8th Floor West, Washington, DC 20447–0002, Phone: 202–401–2344, E-mail: *tichappelle@acf.hhs.gov.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Training and Technical Assistance (T&TA): All potential ANA applicants are eligible to receive T&TA. Prospective applicants should check ANA's Web site for training and technical assistance dates and locations, or contact the ANA Help Desk at 1–877–922–9262.

Please reference *Section IV.3* for details about acknowledgement of received applications.

Dated: May 24, 2005.

Kimberly Romine,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. 05–11279 Filed 6–6–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0526]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 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 July 7, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (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: 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 a potential to address an unmet medical need. Under FDAMA 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 the following 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 act, an applicant who seeks fast track designation is required to submit a request to the agency showing that the product may do the following: (1) 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 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 already 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. 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 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) 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 number 0910–0014, expires January 31, 2006); 356h (OMB control number 0910–0338, expires August 31, 2005); and 3397 (OMB control number 0910–0297, expires December 31, 2006).

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 56. To obtain this estimate, FDA averaged the number of requests for fast track designation received by CBER and CDER in the 3-year period from 2001 to 2003. For these 3 years, CBER and CDER together received a yearly average of 67 requests from 56 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 67 requests made per year, the agency granted 47 requests for fast track designation. For each of the 47 granted requests, FDA estimates that a premeeting package was submitted to the agency. 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.

In the **Federal Register** of December 13, 2004 (69 FR 72202), FDA published a 60-day notice requesting public comment on the information collection

provisions. One comment was received but was not related to the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Designation Request	56	1.20	67	60	4,020
Premeeting Packages	47	1.00	47	100	4,700
Total					8,720

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

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11206 Filed 6–6–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program

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 July 7, 2005.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amends section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374) by adding paragraph (g). This amendment authorizes FDA to establish a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. Under this new Inspection by Accredited Persons Program (AP program), such manufacturers may elect to have third parties that have been accredited by FDA (accredited person or AP) conduct some of their inspections instead of FDA.

The AP program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

The applicant must submit the following information in support of a request for approval to use an AP:

- Information that shows that the applicant ''manufactures, prepares, propagates, compounds, or processes'' class II or class III medical devices.
- Information that shows that the applicant markets at least one of the devices in the United States.
- Information that shows that the applicant markets or intends to market at least one of the devices in one or more foreign countries and one or both of the following two conditions are met as follows:

1. One of the foreign countries certifies, accredits, or otherwise recognizes the AP the applicant has selected as a person authorized to conduct inspections of device establishments; or

2. A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection by the FDA or by the AP.

- Information that shows that the applicant's most recent inspection performed by FDA, or by an AP under this program, was classified by FDA as either ''No Action Indicated (NAI)'' or ''Voluntary Action Indicated (VAI);'' and
- A notice to FDA requesting clearance (approval) to use an AP, and identifying the AP the applicant selected.

In the **Federal Register** of June 3, 2004 (69 FR 31397 at 31398), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment concerning the potential burden associated with the third party inspectional program application process if related cumulative partial inspections over a 2-year period were not recognized by FDA as a single comprehensive inspection. FDA clarified the guidance to state that manufacturers may rely on a single comprehensive inspection or a serious of partial inspections that would cumulatively constitute a complete inspection for the purposes of meeting FDA's biennial inspection requirement. Reapplication to the FDA AP inspection program will not be necessary to conduct each related partial inspection that cumulatively constitutes a single comprehensive inspection of an establishment.

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