www.fda.gov/dockets/ecomments. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Avis Danishefsky, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, ext. 161.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying sirolimus test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for sirolimus test systems.

Many aspects of this guidance document, especially those concerning performance characteristics and risks to health, were developed using information FDA obtained from the Therapeutic Drug Management and Toxicology Roundtable, a working group composed of representatives from laboratory medicine and device manufacturers.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on sirolimus test systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Sirolimus Test Systems'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1300) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–22012 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: HRSA AIDS Drug Assistance Program Quarterly Report—New

HRSA's AIDS Drug Assistance Program (ADAP) is funded through Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which provides grants to States and Territories. The ADAP provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 states, the District of Columbia, and several territories receive ADAP grants. As part of the funding requirements, ADAP grantees submit quarterly reports that include

information on patients served, pharmaceuticals prescribed, pricing, and other sources of support to provide AIDS medication treatment, eligibility requirements, cost data, and coordination with Medicaid. Each quarterly report requests updates from programs on number of patients served, type of pharmaceuticals prescribed, and prices paid to provide medication. The first quarterly report of each ADAP fiscal year (due in July of each year) also requests information that only changes annually (*e.g.*, State funding, drug formulary, eligibility criteria for enrollment, and cost-saving strategies including coordinating with Medicaid).

The quarterly report represents the best method for HRSA to determine how ADAP grants are being expended and how to provide answers to requests from Congress and other organizations. This new quarterly report will replace two current monthly progress reports plus information currently submitted annually. The new quarterly report should reduce burden, avoid duplication of information, and provide HRSA information in a form that easily lends itself to responding to inquiries.

The estimated annual burden per ADAP grantee is as follows:

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
First quarterly report	57	1	57	3	171
Second, third, & fourth quarterly reports	57	3	171	1.5	256.5
Total	57		228		427.5

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 23, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–21921 Filed 9–29–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

''Closing the Health Gap''—Sudden Infant Death Syndrome and Infant Mortality Initiative

AGENCY: Indian Health Service, HHS.

ACTION: Notice of Intent to Award for Single Source Award with the Aberdeen Area Tribal Chairman's Health Board Northern Plains Healthy Start Project.

Recipient: Aberdeen Tribal Chairman's Health Board Northern Plains Healthy Start Project.

Purpose of the Award: The Indian Health Service (IHS) announces an award for single source award as established under the authority of Section 301(a) of the Public Health Service Act, as amended. The single source award is to support the Aberdeen Area Indian Health Service tribal organization, not the IHS. The Aberdeen Area Tribal Chairman's Health Board and its program the Northern Plains Healthy Start Project (NPHSP) meet the eligibility criteria for CFDA 93.933 as a demonstration project for the expressed purpose of promoting and improving health and health care services in tribal communities. The award is part of a larger Office of Minority Health initiative entitled ''Closing the Health Gap'' with the expressed purpose of addressing elevated infant mortality, a known health disparity for American Indians and Alaska Natives. NPHSP has been in existence for twelve years. Increased emphasis will be placed on case management and community measures to address maternal and infant health promotion and reduction of risk factors associated with sudden Infant Death Syndrome and infant mortality (SIDS/IM).

Amount of Award: $450,000 in funds will be awarded.

Project Period: There will be only one funding cycle during Fiscal Year (FY) 2004. The project will be funded in annual budget periods for up to three years depending on the defined scope of work. Continuation of the project will be based on the availability of appropriations in future years, the continuing need the IHS has for the projects, and satisfactory project performance. The Project period will run from October 1, 2004 to September 30, 2007.

Justification for the Exception to the Competition: The IHS Area with the highest IMR and SIDS rates is the Aberdeen Area. This Area includes Tribes situated in the states of Iowa, Nebraska, North Dakota and South Dakota. The Aberdeen Area Tribal Chairman's Health Board maintains a 501(c)3 status and is comprised of representatives of eighteen Tribes, sixteen of which participate in the NPHSP. NPHSP is a program within the Aberdeen Tribal Chairman's Health Board and operates in the four states. The project consists of home based interventions in the form of case management to high risk prenatal American Indian women. NPHSP has served targeted perinatal populations and their families and communities for twelve years. No other tribal program representing such a broad consortia exists. General long-term program goals of the Northern Plains Health Start Project are in alignment with those of the Office of Minority Health ''Closing the Health Gap—SIDS/IMR Initiative.''

Agency Contacts: For program information, contact: Judith Thierry, D.O., Maternal and Child Health Coordinator, Office of Public Health, IHS, 801 Thompson Avenue, Suite 300, Rockville, Maryland 20852; (301) 443–5070; *jthierry@na.ihs.gov;* or (301) 594–6213 (fax). For grant and business information, contact Ms. Martha Redhouse, Grants Management Specialist, Division of Grants Policy, IHS, 801 Thompson Avenue, Suite 120, Rockville, MD 20852; (301) 443–5204. (The telephone numbers for Dr. Thierry and Ms. Redhouse are not toll-free).

Dated: September 24, 2004.

Robert G. McSwain,

Acting Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 04–21891 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Inventory and Evaluation of Clinical Networks

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of