gopher.cder.fda.gov and select the ''Industry Guidance'' menu option. For WWW, connect to the FDA home page at http://www.fda.gov.

Submit written comments on the documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Corporations should submit two copies of any comments and individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Copies of the documents and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074, or

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852–1420, 301–594–5417.

SUPPLEMENTARY INFORMATION: The President's November 1995 report, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' outlined changes to the biologics regulations designed to reduce the burden of FDA regulations on industry without reducing public health protection. One of the recommended modifications was to have investigational new drug (IND) reviewers respond within 30 days whether newly submitted information supports the initiation or continuation of a human investigation that the agency has put on clinical hold.

Companies or individuals that intend to study IND's or biologics in humans generally are required first to submit an IND application to the agency. They may proceed with the study 30 days after the agency receives the application unless FDA puts the study on clinical hold (§ 312.42 (21 CFR 312.42).) Section 312.42(a) describes a clinical hold as an ''order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation.'' Section 312.42(d) states that the hold may be relayed to the sponsor by telephone or other rapid means of communication and that FDA will provide a written explanation of the basis of the hold to the sponsor no more than 30 days following the hold. Though § 312.42(d) allows for communication of the reasons for a hold within 30 days following the placement of the hold, both CBER and CDER provide this notification in even shorter timeframes, consistent with the procedures set forth in the CBER and CDER documents. Thus, a researcher or company that intends to begin testing a biologic or new drug in humans, may not begin or continue the study until FDA releases the clinical hold. Removal of the hold may be relayed by telephone or other rapid means of communication unless FDA notified the sponsor in writing that once a correction or modification was made they could proceed as outlined in § 312.42(e).

In the past, FDA had no internal operating procedures regarding how much time it may take to evaluate data submitted by the sponsor in response to the clinical hold. FDA is committed to promptly reviewing and responding to data submitted in response to a clinical hold and to do so within 30 days of receiving the submission. FDA believes that the 30-day period meets the needs of sponsors, will prevent delays during review of data, and will prevent unnecessary delays in the start or continuation of clinical studies. These procedures are contained in CBER's Policy and Procedure Guide, OD–R–8–96, ''Centerwide Policy on Issuance of and Response to Clinical Hold Letters for Investigational New Drug Applications,'' dated August 20, 1996, and in CDER's Manual of Policies and Procedures, MAPP 6030.1, ''IND Process and Review Procedures,'' dated June 20, 1996.

Although these documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public, they do represent the agency's current thinking on time periods for the review and response to materials submitted in response to clinical hold for IND's.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the procedure documents. FDA will review the comments received and, if appropriate, consider preparing revised documents based upon that review. Corporations should submit two copies of any comments and individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Copies of the documents and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–30770 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish 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 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

Voluntary Customer Surveys of ''Partners'' of the Health Resources and Services Administration—NEW

In response to Executive Order 12862, Setting Customer Service Standards, the Health Resources and Services Administration (HRSA) is proposing to conduct voluntary customer surveys of its ''partners'' to assess strengths and weaknesses in program services. HRSA partners are typically State or local governments, health care facilities, health care consortia, health care providers, and researchers. Partner surveys to be conducted by HRSA might include, for example, surveys of grantees to determine satisfaction with the technical assistance, or surveys of providers who receive training from HRSA grantees to measure satisfaction with the training experience. Results of

these surveys will be used to plan and redirect resources and efforts as needed to improve service. A generic approval will be requested from OMB to conduct partner surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred methodologies. An estimate of annual burden is shown below.

Type of survey	Number of respondents	Responses per respondent	Average burden/response (hours)	Total hours of burden
In-class evaluations	40,000	1	0.05	2,000
Mail/telephone surveys	6,000	1	0.25	1,500
Focus groups	100	1	1.5	150
Total	46,100	1	0.08	3,650

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 26, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–30725 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–15–P

Indian Health Service

Availability of Funds for Loan Repayment Program for Repayment of Health Professions Educational Loans

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: The Indian Health Service (IHS) announces that approximately $11,706,000 in funds for fiscal year (FY) 1997 is available for the repayment of health professions educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs. The IHS estimates that 250 loan repayment awards averaging $50,000 per award may be made with this funding.

Funds are required to be expended by September 30 of the fiscal year. This program is authorized by Section 108 of the Indian Health Care Improvement Act (IHCIA) as amended, 25 U.S.C. 1601 et seq. The IHS invites potential applicants to request an application for participation in the Loan Repayment Program.

DATE: Applications for the FY 1997 Loan Repayment Program will be accepted and evaluated monthly beginning January 2, 1997 and will continue each month thereafter until all funds are exhausted. Subsequent monthly deadline dates are scheduled for Friday of the second full week of each month. Notice of awards will be mailed on the last working day of each month.

Applicants selected for participation in the FY 1997 program cycle will be expected to begin their service period no later than September 30, 1997.

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall *not* be acceptable as proof of timely mailing.)

Applications received after the monthly closing date will be held for consideration in the next monthly funding cycle. Applicants who do not receive funding by September 30, 1997 will be notified in writing.

FORM TO BE USED FOR APPLICATION: Applications will be accepted only if they are submitted on the form entitled ''Application for the Indian Health Service Loan Repayment Program,'' identified with the Office of Management and Budget approval number of OMB #0917–0014 (expires 11/30/99).

ADDRESS: Application materials may be obtained by calling or writing to the address below. In addition, completed applications should be returned to: IHS Loan Repayment Program, 12300 Twinbrook Parkway—Suite 100, Rockville, Maryland 20852, PH: 301/443–3396 [between 8:00 a.m. and 5:00 p.m. (EST) Monday through Friday, except Federal holidays].

FOR FURTHER INFORMATION CONTACT: Please address inquires to Mr. Charles Yepa, Chief, IHS Loan Repayment Program, Twinbrook Metro Plaza—Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852, PH: 301/443–3396 [between 8:00 a.m. and 5:00 p.m. (EST) Monday through Friday, except Federal holidays].

SUPPLEMENTARY INFORMATION: Section 108 of the IHCIA as amended by Public Laws 100–713 and 102–573, authorizes the IHS Loan Repayment Program and provides in pertinent part as follows:

The Secretary, acting through the Service, shall establish a program to be known as the Indian Health Service Loan Repayment Program (hereafter referred to as the ''Loan Repayment Program'') in order to assure an adequate supply of trained health professionals necessary to maintain accreditation of, and provide health care services to Indians through, Indian health programs.

Section 4(n) of the IHCIA, as amended by the Indian Health Care Improvement Technical Corrections Act of 1996, Pub. L. 104–313, provides that:

''Health Profession'' means allopathic medicine, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public health nursing, dentistry, psychiatry, osteopathy, optometry, pharmacy, psychology, public health, social work, marriage and family therapy, chiropractic medicine, environmental health and engineering, an allied health profession, or any other health profession.

For the purposes of this program, the term ''Indian health program'' is defined in Section 108(a)(2)(A), as follows:

. . . any health program or facility funded, in whole or in part, by the IHS for the benefit of American Indians and Alaska Natives and administered:

a. Directly by the service; or

b. By any Indian tribe or tribal or Indian organization pursuant to a contract under:

(1) The Indian Self-Determination Act; or

(2) Section 23 of the Act of April 30, 1908, (25 U.S.C. 47), popularly known as the Buy Indian Act; or

(3) By an urban Indian organization pursuant to Title V of this act.

Applicants may sign contractual agreements with the Secretary for 2 years. The IHS will repay all or a portion of the applicant's health professions educational loans (undergraduate and graduate) for tuition expenses and reasonable educational and living expenses in amounts up to $30,000 per year for each year of contracted service to be made in annual payments to the participant for the purpose of repaying his/her outstanding health professions educational loans. Repayment of health professions educations loans will be made to the