the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 018310 for LYMPHAZURIN (isosulfan blue) Injectable in the **Federal Register** of December 5, 2014 (79 FR 72186) and NDA 020151 for EFFEXOR (venlafaxine HCl) Tablets in the **Federal Register** of July 19, 2013 (78 FR 43210).)

Application No.	Drug	Applicant
NDA 018310	LYMPHAZURIN (isosulfan blue) Injectable; Injection, 1%	Covidien, 60 Middletown Ave., North Haven, CT 06473.
NDA 019966	TEMOVATE (clobetasol propionate) Solution; Topical, 0.05%.	Fougera Pharmaceuticals Inc., 1 Health Plaza, Bldg. 434, East Hanover, NJ 07936.
NDA 020151	EFFEXOR (venlafaxine hydrochloride (HCl)) Tablet; Oral, Equivalent to (EQ) 12.5 milligram (mg) Base; EQ 25 mg Base; EQ 37.5 mg Base; EQ 50 mg Base; EQ 75 mg Base; EQ 100 mg Base.	Wyeth Pharmaceuticals Inc., 235 East 42nd St., New York, NY 10017.
NDA 020214	ZEMURON (rocuronium bromide) Injectable; Injection 100 mg/10 milliliter (mL); 50 mg/5 mL; 10 mg/mL.	Organon USA Inc., 351 North Sunmeytown Pike, North Wales, PA 19454.
NDA 021040	PREFEST (estradiol; norgestimate) Tablet; Oral, 1 mg, 1 mg/0.09 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.
NDA 021621	CHILDREN'S ZYRTEC ALLERGY (cetirizine HCl) and CHILDREN'S ZYRTEC HIVES RELIEF (cetirizine HCl) Chewable Tablet; Oral, 5 mg; 10 mg.	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034.
NDA 050783	PERIOSTAT (doxycycline hyclate) Tablet; Oral, EQ 20 mg Base.	Galderma Laboratories, L.P., 14501 North Freeway, Fort Worth, TX 76177.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01859 Filed 1–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than March 4, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Evaluation and Initial Assessment of the HRSA Teaching Health Centers Graduate Medical Education Program.

OMB No. 0906–xxxx—New.

Abstract: Section 5508 of the Affordable Care Act of 2010 amended section 340H of the Public Health Service Act to establish the Teaching Health Center Graduate Medical Education (THCGME) program to provide funding support for new and

the expansion of existing primary care residency training programs in community-based settings. The primary goals of this program are to increase the production of primary care providers who are better prepared to practice in community settings, particularly with underserved populations, and improve the geographic distribution of primary care providers.

Statute requires the Secretary to determine an appropriate THCGME program payment for indirect medical expenses (IME) as well as to update, as deemed appropriate, the per resident amount used to determine the Program's payment for direct medical expenses (DME). To inform these determinations and to increase understanding of this model of residency training, the George Washington University (GW) is conducting an evaluation of the costs associated with training residents in the Teaching Health Center (THC) model. GW has developed a standardized costing instrument to gather data from all THCGME programs. The information gathered in the standardized costing instrument includes, but is not limited to, resident and faculty full-time equivalents, salaries and benefits, residency administration costs, educational costs, residency clinical operations and administrative costs, and patient visits and clinical revenue generated by medical residents.

Need and Proposed Use of the Information: HRSA is collecting costing information related to both DME and IME in an effort to establish a THC's total cost of running a residency program, to assist the Secretary in determining an appropriate update to the per resident amount used to calculate the payment for DME and an appropriate IME payment. The described data collection activities will serve to inform these statutory requirements for the Secretary in a uniform and consistent manner.

Likely Respondents: THCGME grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Teaching Health Center Costing Instrument	60	1	60	10	600
Total	60	1	60	10	600

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–01882 Filed 1–30–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[CFDA Number: 93.164]

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

DATES: *Key Dates:* February 13, 2015 first award cycle deadline date; August 14, 2015 last award cycle deadline date; September 11, 2015 last award cycle deadline date for supplemental loan repayment program funds; September 30, 2015 entry on duty deadline date.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2015 includes $16,721,135 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service as defined in the IHS LRP policy clarifications at *http://www.ihs.gov/loanrepayment/documents/LRP_Policy_Updates.pdf* in Indian health programs.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by the Indian Health Care Improvement Act (IHCIA) Section 108, codified at 25 U.S.C. 1616a.

II. Award Information

The estimated amount available is approximately $16,721,135 to support approximately 387 competing awards averaging $43,182 per award for a two year contract. One year contract extensions will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2015 program cycle will be expected to begin their service period no later than September 30, 2015.

III. Eligibility Information

A. Eligible Applicants

Pursuant to 25 U.S.C. 1616(b), to be eligible to participate in the LRP, an individual must:

(1)(A) Be enrolled —

(i) In a course of study or program in an accredited institution, as determined by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in such program; or

(ii) In an approved graduate training program in a health profession; or

(B) Have a degree in a health profession and a license to practice in a State; and

(2)(A) Be eligible for, or hold an appointment as a commissioned officer in the Regular Corps of the Public Health Service (PHS); or

(B) Be eligible for selection for service in the Regular Corps of the PHS; or

(C) Meet the professional standards for civil service employment in the IHS; or

(D) Be employed in an Indian health program without service obligation; and

(E) Submit to the Secretary an application for a contract to the LRP. The Secretary must approve the contract before the disbursement of loan repayments can be made to the participant. Participants will be required to fulfill their contract service agreements through full-time clinical practice at an Indian health program site determined by the