Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04013 Filed 2–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1600]

Draft Guidance for Industry and Tobacco Retailers; Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent.'' This draft guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to not substantially equivalent (NSE) orders issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 28, 2014.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for tobacco retailers entitled ''Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent.'' In this draft guidance, FDA provides information on its enforcement policy regarding so-called provisional tobacco products that become subject to NSE orders under the FD&C Act. The provisional products addressed by this draft guidance are tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a section 905(j) (21 U.S.C. 387e(j)) (or substantial equivalent) report was submitted no later than March 22, 2011. Because the FD&C Act permitted this specific group of products to remain on the market pending FDA's review of the report, there will very likely be products at retail locations within the United States when FDA issues an order finding a tobacco product NSE. This draft guidance explains that FDA does not intend to take enforcement action for at least 30 calendar days from the date the NSE order issues for those products that are in the retailer's current inventory at a specific retail location on the date FDA issues the NSE order.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent.'' 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 statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03978 Filed 2–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Loan Repayment Program for Repayment ofHealth Professions Educational Loans

Announcement Type: Initial.

CFDA Number: 93.164.

Key Dates: February 14, 2014 first award cycle deadline date; August 15, 2014 last award cycle deadline date; September 12, 2014 last award cycle deadline date for supplemental loan repayment program funds; September 30, 2014 entry on duty deadline date.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2014 includes $19,090,023 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 25 U.S.C. 1616a.

II. Award Information

The estimated amount available is approximately $19,090,023 to support approximately 440 competing awards averaging $43,358 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 2014 program cycle will be expected to begin their service period no later than September 30, 2014.

III. Eligibility Information

A. Eligible Applicants

Pursuant to Section 108(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 Secretary. Loan repayment sites are characterized by physical, cultural, and professional isolation, and have histories of frequent staff turnover. Indian health program sites are annually prioritized within the Agency by discipline, based on need or vacancy. The IHS LRP's ranking system gives high site scores to those sites that are most in need of specific health professions. Awards are given to the applications that match the highest priorities until funds are no longer available.

Any individual who owes an obligation for health professional service to the Federal Government, a State, or other entity is not eligible for the LRP unless the obligation will be completely satisfied before they begin service under this program.

Section 108 of the IHCIA, as amended, authorizes the IHS LRP and provides in pertinent part as follows:

(a)(1) The Secretary, acting through the Service, shall establish a program to be known as the Indian Health Service Loan Repayment Program (hereinafter 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 1603(10) of the IHCIA provides that:

''Health Profession'' means allopathic medicine, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public healthnursing, 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:

(A) The term Indian health program means any health program or facility funded, in whole or in part, by the Service for the benefit of Indians and administered—

(i) Directly by the Service;

(ii) By any Indian Tribe or Tribal or Indian organization pursuant to a contract under—

(I) The Indian Self-Determination Act, or

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

(iii) By an urban Indian organization pursuant to Title V of this Act.

Section 108 of the IHCIA, as amended, authorizes the IHS to determine specific health professions for which IHS LRP contracts will be awarded. Annually, the Director, Division of Health Professions Support, sends a letter to the Director, Office of Public Health, Tribal leaders, and urban Indian health programs directors to request a list of positions for which there is a need or vacancy. The list of priority health professions that follows is based upon the needs of the IHS as well as upon the needs of American Indians and Alaska Natives.

(a) Medicine: Allopathic and Osteopathic.

(b) Nurse: Associate, B.S., and M.S. Degree.

(c) Clinical Psychology: Ph.D. and Psy.D.

(d) Counseling Psychology: Ph.D.

(e) Social Work: Licensed Clinical Social Worker; Masters level only.

(f) Chemical Dependency Counseling: Baccalaureate and Masters level.

(g) Counseling: Masters level only.

(h) Dentistry: DDS and DMD.

(i) Dental Hygiene.

(j) Dental Assistant: Certified.

(k) Pharmacy: B.S., Pharm.D.

(l) Optometry: O.D.

(m) Physician Assistant: Certified.

(n) Advanced Practice Nurses: Nurse Practitioner, Certified Nurse Midwife, Doctor of Nursing, Registered Nurse Anesthetist (Priority consideration will be given to Registered Nurse Anesthetists.).

(o) Podiatry: D.P.M.

(p) Physical Rehabilitation Services: Physical Therapy, Occupational Therapy, Speech-Language Pathology, and Audiology: M.S. and D.P.T.

(q) Diagnostic Radiology Technology: Certificate, Associate, and B.S.

(r) Medical Laboratory Scientist, Medical Technology, Medical Laboratory Technician: Associate, and B.S.

(s) Public Health Nutritionist/ Registered Dietitian.

(t) Engineering (Environmental): B.S. (Engineers must provide environmental engineering services to be eligible.).

(u) Environmental Health (Sanitarian): B.S. and M.S.

(v) Health Records: R.H.I.T. and R.H.I.A.

(w) Certified Professional Coder: AAPC or AHIMA.

(x) Respiratory Therapy.

(y) Ultrasonography.

(z) Chiropractors: Licensed.

(aa) Naturopathic Medicine: Licensed.

(bb) Acupuncturists: Licensed.

B. Cost Sharing or Matching

Not applicable.

C. Other Requirements

Interested individuals are reminded that the list of eligible health and allied health professions is effective for applicants for FY 2014. These priorities will remain in effect until superseded.

IV. Application and Submission Information

A. Content and Form of Application Submission

Each applicant will be responsible for submitting a complete application. Go to *http://www.ihs.gov/loanrepayment* for more information on how to apply electronically. The application will be considered complete if the following documents are included:

- Employment Verification—Documentation of your employment with an Indian health program as applicable:
  - Commissioned Corps orders, Tribal employment documentation or offer letter, or notification of Personnel Action (SF–50)—For current Federal employees.

• License to Practice—A photocopy of your current, non-temporary, full and unrestricted license to practice (issued by any state, Washington, DC or Puerto Rico).

• Loan Documentation—A copy of all current statements related to the loans submitted as part of the LRP application.

• If applicable, if you are a member of a Federally recognized Tribe or Alaska Native (recognized by the Secretary of the Interior), provide a certification of Tribal enrollment by the Secretary of the Interior, acting through the Bureau of Indian Affairs (BIA) (Certification: Form 4432 Category A—Members of Federally-Recognized Indian Tribes, Bands or Communities).

B. Submission Dates and Address

Applications for the FY 2014 LRP will be accepted and evaluated monthly beginning February 14, 2014, and will continue to be accepted each month thereafter until all funds are exhausted for FY 2014. Subsequent monthly deadline dates are scheduled for Friday of the second full week of each month until August 15, 2014.

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

(1) Received on or before the deadline date; and

(2) All documentation as described above are submitted 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 are not acceptable as proof of timely mailing).

Applications submitted 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, 2014, will be notified in writing.

Application documents should be sent to: IHS Loan Repayment Program, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852.

C. Intergovernmental Review

This program is not subject to review under Executive Order 12372.

D. Funding Restrictions

Not applicable.

E. Other Submission Requirements

New applicants are responsible for using the online application. Applicants requesting a contract extension must do so in writing as early in the fiscal year in which they are reapplying.

V. Application Review Information

A. Criteria

The IHS has identified the positions in each Indian health program for which there is a need or vacancy and ranked those positions in order of priority by developing discipline-specific prioritized lists of sites. Ranking criteria for these sites may include the following:

(1) Historically critical shortages caused by frequent staff turnover;

(2) Current unmatched vacancies in a health profession discipline;

(3) Projected vacancies in a health profession discipline;

(4) Ensuring that the staffing needs of Indian health programs administered by an Indian Tribe or Tribal health organization or urban Indian organization receive consideration on an equal basis with programs that are administered directly by the Service; and

(5) Giving priority to vacancies in Indian health programs that have a need for health professionals to provide health care services as a result of individuals having breached LRP contracts entered into under this section.

Consistent with this priority ranking, in determining applications to be approved and contracts to accept, the IHS will give priority to applications made by American Indians and Alaska Natives and to individuals recruited through the efforts of Indian Tribes or Tribal or Indian organizations.

B. Review and Selection Process

Loan repayment awards will be made only to those individuals serving at facilities which have a site score of 70 or above during the first quarter of FY 2014, if funding is available.

One or all of the following factors may be applicable to an applicant, and the applicant who has the most of these factors, all other criteria being equal, will be selected.

(1) An applicant's length of current employment in the IHS, Tribal, or urban program.

(2) Availability for service earlier than other applicants (first come, first served).

(3) Date the individual's application was received.

C. Anticipated Announcement and Award Dates

Not applicable.

VI. Award Administration Information

A. Award Notices

Notice of awards will be mailed on the last working day of each month. Once the applicant is approved for participation in the LRP, the applicant will receive confirmation of his/her loan repayment award and the duty site at which he/she will serve his/her loan repayment obligation.

B. Administrative and National Policy Requirements

Applicants may sign contractual agreements with the Secretary for two years. The IHS may repay all, or a portion of the applicant's health profession educational loans (undergraduate and graduate) for tuition expenses and reasonable educational and living expenses in amounts up to $20,000 per year for each year of contracted service. Payments will be made annually to the participant for the purpose of repaying his/her outstanding health profession educational loans. Payment of health profession education loans will be made to the participant within 120 days, from the date the contract becomes effective. The effective date of the contract is calculated from the date it is signed by the Secretary or his/her delegate, or the IHS, Tribal, urban, or Buy Indian health center entry-on-duty date, whichever is more recent.

In addition to the loan payment, participants are provided tax assistance payments in an amount not less than 20 percent and not more than 39 percent of the participant's total amount of loan repayments made for the taxable year involved. The loan repayments and the tax assistance payments are taxable income and will be reported to the Internal Revenue Service (IRS). The tax assistance payment will be paid to the IRS directly on the participant's behalf. LRP award recipients should be aware that the IRS may place them in a higher tax bracket than they would otherwise have been prior to their award.

C. Contract Extensions

Any individual who enters this program and satisfactorily completes his or her obligated period of service may apply to extend his/her contract on a year-by-year basis, as determined by the IHS. Participants extending their contracts may receive up to the maximum amount of $20,000 per year plus an additional 20 percent for Federal withholding.

VII. Agency Contact

Please address inquiries to Ms. Jacqueline K. Santiago, Chief, IHS Loan Repayment Program, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852, Telephone: 301/443–3396 [between 8:00 a.m. and 5:00 p.m. (EST)

Monday through Friday, except Federal holidays].

VIII. Other Information

IHS Area Offices and Service Units that are financially able are authorized to provide additional funding to make awards to applicants in the LRP, but not to exceed $35,000 a year plus tax assistance. All additional funding must be made in accordance with the priority system outlined below. Health professions given priority for selection above the $20,000 threshold are those identified as meeting the criteria in 25 U.S.C. 1616a(g)(2)(A) which provides that the Secretary shall consider the extent to which each such determination:

(i) Affects the ability of the Secretary to maximize the number of contracts that can be provided under the LRP from the amounts appropriated for such contracts;

(ii) Provides an incentive to serve in Indian health programs with the greatest shortages of health professionals; and

(iii) Provides an incentive with respect to the health professional involved remaining in an Indian health program with such a health professional shortage, and continuing to provide primary health services, after the completion of the period of obligated service under the LRP.

Contracts may be awarded to those who are available for service no later than September 30, 2014, and must be in compliance with any limits in the appropriation and Section 108 of the IHCIA not to exceed the amount authorized in the IHS appropriation (up to $32,000,000 for FY 2014). In order to ensure compliance with the statutes, Area Offices or Service Units providing additional funding under this section are responsible for notifying the LRP of such payments before funding is offered to the LRP participant.

Should an IHS Area Office contribute to the LRP, those funds will be used for only those sites located in that Area. Those sites will retain their relative ranking from the national site-ranking list. For example, the Albuquerque Area Office identifies supplemental monies for dentists. Only the dental positions within the Albuquerque Area will be funded with the supplemental monies consistent with the national ranking and site index within that Area.

Should an IHS Service Unit contribute to the LRP, those funds will be used for only those sites located in that Service Unit. Those sites will retain their relative ranking from the national site-ranking list. For example, Whiteriver Service Unit identifies supplemental monies for nurses. The Whiteriver Service Unit consists of two facilities, namely the Whiteriver PHS Indian Hospital and the Cibecue Indian Health Center. The national ranking will be used for the Whiteriver PHS Indian Hospital (Score = 79) and the Cibecue Indian Health Center (Score = 95). With a score of 95, the Cibecue Indian Health Center would receive priority over the Whiteriver PHS Indian Hospital.

Dated: February 14, 2014.

Yvette Roubideaux,

Acting Director,Indian Health Service.

[FR Doc. 2014–04075 Filed 2–24–14; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods for Amelioration and Treatment of Pathogen-Associated Inflammatory Response

Description of Technology: This CDC invention provides methods for preventing or treating inflammatory response-linked, infection induced pathologies, which are mediated by endogenous substance P. Substance P is a naturally-occurring and major pro-inflammatory neuromediator or neuromodulator, and elevated levels of substance P have been implicated in numerous inflammation-associated diseases. More specifically, this technology entails administration of anti-substance P antibodies or anti-substance P antibody fragments to a subject in need, thereby inhibiting the activity of endogenous substance P.

Small molecule anti-inflammatory agents currently employed to treat inflammation frequently cause adverse side effects, such as gastrointestinal discomfort and decreased blood clotting efficiency. Use of steroid-based anti-inflammatory drugs may result in reduced adrenal gland function and generalized immune system inhibition. This technology specifically targets and alleviates substance P-induced hyper-inflammatory diseases, potentially avoiding the complications associated with other anti-inflammatory compounds. Blocking the activity of endogenous substance P potentially can be employed to prevent or treat a wide variety of diseases or syndromes caused in whole or part by an inflammatory response mediated by substance P. These include, but are not limited to, virus-mediated bronchiolitis including that mediated by respiratory syncytial virus, bacterial colitis, inflammation associated with chlamydial diseases, lung injury associated with staphylococcal enterotoxin B, inflammation due to cytomegalovirus or hepatitis B virus, sepsis, allergic diseases such as asthma, autoimmune diseases such as rheumatoid arthritis, pancreatitis, inflammatory bowel disease, inflammation associated with multiple sclerosis, and rejection of allografts and other transplanted tissues or organs.

Potential Commercial Applications:

- Treatment of pathogen induced inflammation, especially bronchiolitis
- Prevention or lessening of adverse effects associated with other anti-inflammatory agents
- Amelioration of pain

Competitive Advantages:

- Useful for management of numerous inflammatory-related viral and/or bacterial infections
- May reduce or circumvent adverse side effects associated with other small-molecule and/or steroid-based anti-inflammatory treatments

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors:

Ralph A. Tripp, Larry J. Anderson, Deborah D. Moore (all of CDC)

Publication:

Tripp RA, et al. Respiratory syncytial virus infection and G and/or SH protein expression contribute to substance P, which mediates inflammation and enhanced pulmonary disease in BALB/c