SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ABLAVAR (gadofosveset trisodium). ABLAVAR is indicated for use as a contrast agent in magnetic resonance angiography to evaluate aortoiliac occlusive disease in adults with known or suspected peripheral vascular disease. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ABLAVAR (U.S. Patent Nos. 6,676,929 and 7,060,250) from Epix Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ABLAVAR represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ABLAVAR is 4,508 days. Of this time, 2,673 days occurred during the testing phase of the regulatory review period, while 1,835 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 21, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 21, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 15, 2003. FDA has verified the applicant's claim that the new drug application (NDA) 21–711 was submitted on December 15, 2003.

3. *The date the application was approved*: December 22, 2008. FDA has verified the applicant's claim that NDA 21–711 was approved on December 22, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,806 days of patent term extension for U.S. Patent No. 6,676,929 and 924 days of patent term extension for U.S. Patent No. 7,060,250.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 9, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 6, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010–13655 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Funding Opportunity: Affordable Care Act Medicare Beneficiary Outreach and Assistance Program Funding for Title VI Native American Programs

Purpose of Notice: Availability of funding opportunity announcement.

Funding Opportunity Title/Program Name: Affordable Care Act Medicare Beneficiary Outreach and Assistance Program Funding for Title VI Native American Programs.

Announcement Type: Initial.

Funding Opportunity Number: HHS–2010–AoA–MI–1022.

Statutory Authority: The Medicare Improvements for Patients and Providers Act of 2008—Section 119, Public Law 110–275 as amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.071. Discretionary Projects

DATES: The deadline date for the submission of applications is July 30, 2010.

I. Funding Opportunity Description

AoA will provide a grant of $1,000 to each Older Americans Act Title VI Native American program awardee. The purpose of these grants will be for the coordination of at least one community announcement and at least one outreach event to inform and assist eligible Native American elders about the benefits available to them through Medicare Part D, the Low Income Subsidy, the Medicare Savings Program, or Medicare prevention benefits and screenings. The example of $1,000 per event is for illustrative purposes only. There is data available from the National Association of Area Agencies on Aging (n4a) and studies performed by the National Council on Aging (NCOA) that reflect these costs for planning and implementing a community event for Medicare Part D and LIS outreach activities.

A detailed description of the funding opportunity may be found at *http://*

www.aoa.gov/doingbus/fundopp/fundopp.aspx

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of grants to Title VI Native American Programs.

2. Anticipated Total Priority Area Funding per Budget Period

AoA intends to make available, under this program announcement, grant awards for $1,000 to 246 projects at a federal share of approximately $246,000 total for a project period of 1 year.

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants

Only current Older Americans Act Title VI Native American Program grantees are eligible to apply for this funding.

2. Cost Sharing or Matching

Cost Sharing does not apply.

3. DUNS Number

All grant applicants must obtain a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number is free and easy to obtain from *http://www.dnb.com/US/duns_update/.*

4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Application and Submission Information

1. Address to Request Application

Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Office for American Indian, Alaskan Native, and Native Hawaiian Programs, Washington, DC 20201, attention: Yvonne Jackson or by calling 202–357–3501, or online at *http://www.grants.gov.*

2. Address for Application Submission

Applications may be submitted by e-mail to *grants.office@aoa.hhs.gov*, by fax to 202–357–3467 or in hard copy by overnight delivery to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, Washington, DC 20201, Attn. Sean Lewis.

3. Submission Dates and Times

To receive consideration, applications must be submitted by 11:59 Eastern time by the deadline listed in the "Dates" section at the beginning of this Notice.

V. Responsiveness Criteria

Does not apply.

VI. Application Review Information

Does not apply.

VII. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration on Aging, Office for American Indian, Alaskan Native, and Native Hawaiian Programs, Washington, DC 20201, attention: Yvonne Jackson or by calling 202–357–3501, or by e-mail at *Yvonne.jackson@aoa.hhs.gov.*

Dated: May 18, 2010.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2010–13651 Filed 6–7–10; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0276]

Guidance for Industry: Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products." The guidance is intended to provide information relating to FDA's enforcement policy concerning section 3 of the Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). This guidance will be implemented immediately, but remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products" 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 guidance.

Submit electronic comments on the 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: Gail Schmerfeld, Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850–3229, 240–276–1717, e-mail: *Gail.Schmerfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 204 of the Tobacco Control Act amended section 3 of the Smokeless Tobacco Act (15 U.S.C. 4402) to prescribe new requirements for health warning labels that must appear on smokeless tobacco product packages and advertising, and to require that rotational warning plans for packaging and advertising for smokeless tobacco products be submitted to FDA, rather than to the Federal Trade Commission (FTC).

The new warning labels required by section 3 of the Smokeless Tobacco Act must begin to rotate in advertising for smokeless tobacco products beginning on June 22, 2010, and must be distributed and displayed on the packaging of smokeless tobacco products manufactured on or after June 22, 2010, as set forth in section 3(b)(3) of the Smokeless Tobacco Act (section 204(b) of the Tobacco Control Act and section 3(b)(3) of the Smokeless Tobacco Act). In addition, on or after July 22, 2010, manufacturers may not introduce any smokeless tobacco product into