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

domestic commerce unless its packaging complies with section 3 of the Smokeless Tobacco Act (Id.). Among the requirements in section 3(b)(3) is that the rotation of label statements on packaging and advertising for each brand of smokeless tobacco must be "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA (Id.).

At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that a smokeless tobacco manufacturer, distributor, importer, or retailer must have an FDA-approved rotational warning plan, so long as a rotational warning plan has been submitted to FDA by July 22, 2010. FDA believes that allowing additional time for the review of rotational warning plans will permit an orderly transition of regulatory authority from FTC to FDA to review and approve rotational warning plans. During such transition between June 22, 2010, and July 22, 2010, affected companies may wish to contact FDA to discuss the submission of their rotational warning plans in order to make the subsequent approval process more orderly and efficient. FDA intends to provide further public notice prior to revising or rescinding this enforcement policy after the transition from FTC to FDA has been accomplished for the submission and review of rotational warning plans. This enforcement policy pertains only to the requirement that smokeless tobacco manufacturers, distributors, importers, or retailers must have an FDA-approved rotational warning plan. FDA expects compliance with regard to all other requirements of section 3 of the Smokeless Tobacco Act, including the requirements relating to size, formatting, location, and use of required warning statements.

II. Significance of Guidance

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115). This guidance is being implemented immediately without prior public comment under 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. This document provides guidance on statutory provisions that take effect June 22, 2010. It is important that FDA explain its enforcement policy concerning the submission and approval of rotational warning plans for smokeless tobacco products before that date.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

An electronic version of this guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: June 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13819 Filed 6–4–10; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0247]

Investigational New Drug Applications; Co-development of Investigational Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain input on methods to co-develop two or more distinct investigational drugs intended to be used in combination to treat a disease or condition. FDA is planning to develop guidance for industry and other affected parties on the co-development of two or more novel drugs intended to be used in combination (but not as not fixed-dose combinations) and is seeking public input to identify the affected parties' information needs concerning such co-development. Accordingly, FDA is seeking comment on general methodologic and regulatory issues that arise in various scenarios when co-developing two or more investigational drugs intended to be used in combination. FDA is also seeking comment on methodologic and regulatory issues when co-developing two or more investigational drugs intended to be used in combination for specific therapeutic areas, including oncology, anti-infectives, seizure disorders, cardiovascular diseases, and any other therapeutic category in which such co-development is likely to occur.

DATES: Submit either electronic or written comments by September 7, 2010.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Colleen L. Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993–0002, 301–796–2270.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is aware of growing interest in co-developing two or more distinct, novel investigational drugs intended to be used in combination to treat a disease or condition (but not as fixed-dose combinations under 21 CFR 300.50). At a September 2009 conference co-hosted by the "Friends of Cancer Research" in partnership with the Engelberg Center for Health Care Reform at the Brookings Institution, and supported by the American Society for Clinical Oncology (ASCO), the American Association for Cancer Research (AACR) Susan G. Komen for the Cure, and the Lance Armstrong Foundation (Brookings Conference), which was attended by FDA scientists, there was considerable interest in approaches to developing new oncology therapies intended to be used in combination. In addition, on April 30, 2010, FDA held a public hearing in accordance with part 15 (21 CFR part 15) devoted, in part, to obtaining information about study designs and appropriate populations for developing two or more novel, direct-acting antivirals intended to be used in combination for the treatment of chronic hepatitis C. FDA is also aware of efforts to try to develop two or more investigational drugs intended to be used in combination to treat tuberculosis. FDA is further aware of general uncertainty about the evidentiary requirements and regulatory criteria applicable to such co-development efforts. Accordingly, FDA is planning to develop generally applicable guidance (not restricted to oncology or any other specific therapeutic category) to address