

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0483]

Guidance for Industry and Food and Drug Administration; Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled, "Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006." The *trans* fat final rule published in the **Federal Register** on July 11, 2003. This guidance document provides guidance to FDA and the food industry about when and how businesses may request the agency to consider enforcement discretion for the use, on products introduced into interstate commerce on or after the January 1, 2006, effective date, of some or all existing label stock that does not declare *trans* fat labeling in compliance with the final rule.

DATES: This guidance is final upon the date of publication. Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julie Moss, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2373, FAX: 301-436-2636.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled "Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006." FDA issued a final rule on July 11, 2003 (68 FR 41434), to require food labels to bear the gram amount of *trans* fat without a percent Daily Value in the Nutrition Facts panel (<http://www.cfsan.fda.gov/~acrobat/fr03711a.pdf>). The *trans* fat final rule becomes effective on January 1, 2006. This guidance document provides guidance to FDA staff and the food industry about when and how businesses may request the agency to consider enforcement discretion for the use, on products introduced into interstate commerce on or after the January 1, 2006 effective date, of some or all existing label stock that does not declare *trans* fat labeling in compliance with the final rule.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), we are making available this guidance that states in plain language the factors the agency intends to consider concerning requests for enforcement discretion by small and other businesses regarding compliance with this regulation.

FDA is issuing this guidance as a level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. This document affects the *trans* fat labeling effective date of January 1, 2006, so it is urgent that FDA explains its new enforcement policy before that date. This guidance represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**

Agreement allows a Tribe to gather information to determine the current types and amounts of Programs, Services, Functions, and Activities (PSFAs), and funding available at the Service Unit, Area, and Headquarters levels and identify programmatic alternatives that will better meet the needs of Tribal members.

II. Award Information

Type of Award: Cooperative Agreement.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2006 is \$600,000 for approximately twelve (12) Tribes to enter the TSGP planning process for compacts beginning in Fiscal Year (FY) 2007 or Calendar Year (CY) 2007. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: The estimated number of awards to be funded is approximately 12.

Project Period: 12 months.

Award Amount: \$50,000 per year.

Programmatic Involvement: IHS TSGP funds will be awarded as cooperative agreements and will have substantial programmatic involvement to establish a basic understanding of IHS Programs, Services, Functions and Activities (PSFAs) as operations at the Service Unit, Area, and Headquarters levels.

The IHS roles and responsibilities will include:

- Identification of IHS staff that will consult with applicants on methods used by the IHS to manage and deliver health care.
- Provide applicants with a list of laws and regulations that provide authority for the various IHS programs.

The Grantee roles and responsibilities will include:

- Research and analysis of the complex IHS budget, at the Service Unit, Area, and Headquarters levels.
- Establishment of a process through which Tribes can effectively approach the IHS to identify programs and associated funding which could be incorporated into programs.

III. Eligibility Information

1. Eligible Applicants

To be eligible for a Planning Cooperative Agreement under this announcement, an applicant must meet all of the following criteria:

A. Be a Federally-recognized Tribe as defined in Title V, Public Law 106-260, Tribal Self-Governance Amendments of 2000, of the Indian Self-Determination and Education Assistance Act (the Act), Public Law 93-638, as amended. However, Alaska Native Villages or

Alaska Native Village Corporations, who are located within the area served by an Alaska Native regional health entity already participating in compact status, are not eligible (Pub. L. 106-260, Title V, section 12(a)(2)).

2. Cost Sharing or Matching Funds

The Self-Governance Planning Cooperative Agreement Announcement does not require matching funds or cost sharing to participate in the competitive grant process.

3. Other Requirements

The following documentation is required (if applicable):

A. This program is described at 93.210 in the *Catalog of Federal Domestic Assistance*. There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria. (Refer to Section III, ELIGIBLE APPLICANTS in this announcement.)

B. Request participation in self-governance by resolution by the governing body of the Indian Tribe. An Indian Tribe that is proposing a cooperative agreement affecting another Indian Tribe must include resolutions from all affected Tribes to be served.

C. Demonstrate, for three fiscal years, financial stability and financial management capability, which is defined as no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's self-determination contracts or self-governance funding agreements with any Federal agency

sections listed below. (The 7 page narrative does not include the work plan, standard forms, Tribal resolution(s), table of contents, budget, budget justifications, narratives, and/or other appendix items.)

Public Policy Requirements: All Federal-wide public policies apply to HHS grants with exception of Lobbying and Discrimination.

3. Submission Dates and Times

Applications must be submitted on-line by January 20, 2006. Late applications not accepted for processing will be returned to the applicant and will not be considered for funding.

4. Intergovernmental Review

This funding opportunity is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." State approval is not required.

5. Funding Restrictions

A. Only one planning cooperative agreement will be awarded per applicant.

A. Each planning cooperative agreement shall not exceed \$50,000. The available funds are inclusive of direct and indirect costs.

B. Planning awards shall not exceed a maximum period of one year.

C. Pre-award costs are not allowable.

6. Other Submission Requirements

The application must comply with the following:

A. Abstract (one page)—Summarizes the project.

B. Application for Federal Assistance (SF-424, Rev. 09/03).

C. Narrative (no more than 7 pages) with time frame chart (one page); pages numbered consecutively, including appendices, and Table of Contents, and should include the following:

(1) Background information on the Tribe.

(1) Objectives and activities that provide a description of what will be accomplished.

(2) A line-item budget and narrative justification.

(3) Appendix to include:

a. Resumes or position descriptions of key staff.

b. Contractors/Consultants resumes or qualifications.

c. Proposed Scope of Work.

Electronic Transmission—The preferred method for receipt of applications is electronic submission through <http://Grants.gov>. However, should any technical problems arise regarding the submission, please contact our Grants Policy Staff at (301) 443-

6528 at least ten days prior to the application deadline. To submit an application electronically, please use the <http://www.Grants.gov> apply site. Download a copy of the application package on the Grants.gov Web site, complete it offline and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- Under the new IHS requirements, paper applications are not the preferred method. However, if you have technical problems submitting your application on-line, and you have contacted the Grants Policy Staff and advised them of the difficulties you are having in submitting your application on-line, and if it is determined by the Grants Policy Staff that the technical difficulties cannot be resolved, you may submit a paper application after you have downloaded the application package from Grants.gov. The paper application may be sent directly to the Division of Grants Operations, 801 Thompson Avenue, TMP 360, Rockville, MD 20852 by the due date, January 20, 2006.

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours

and if the project can be accomplished with expected available resources.

Budget Justification (15 points).

Submit a line-item budget with a brief narrative justification for all expenditures. Are costs identified reasonable and allowable in accordance with OMB Circulars A-87, "Cost Principles for State and Local Governments" and A-122, "Cost Principles for Non-Profit Organizations?"

Management Of Health Program(s) (10 points). Does the applicant propose an improved approach to managing the health program(s) and state/demonstrate how the delivery of quality health services will be maintained under self-governance?

Appendix Items:

- Work plan for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant proposed scope of work (if applicable).
- Indirect Cost Agreement.
- Organizational chart (optional).

2. Review and Selection Process

In addition to the above criteria/requirements, applications are considered according to the following:

A. Application Submission (Application Deadline: January 20, 2006). Applications submitted in advance of or by the deadline and verified by the tracking number will undergo a preliminary review to determine that:

- (1) The applicant and proposed project type is eligible in accordance with this grant announcement.
- (2) The application is not a duplication of a previously funded project.
- (3) The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise, it may be returned.

B. Competitive Review of Eligible Applications (Objective Review: March 8-9, 2006). Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed for merit by the Ad Hoc Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated

and rated on the basis of the evaluation criteria listed in Section V.1. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success, and assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of TSGP funding is not sufficient to support all approved applications. Applications recommended for approval, having a score of 60 or above by the ORC and scored high enough to be considered for funding, are forwarded by the Division of Grants Operations (DGO) for cost analysis and further recommendation. The program official forwards the final approval list to the IHS Director for final review and approval. Applications scoring below 60 points will be disapproved and returned to the applicant.

NOTE: In making the final selections, the IHS Director will consider the ranking factor and the status of the applicant's single audit reports. The comments from the ORC will be advisory only. The IHS Director will make the final decision on awards.

3. Anticipated Award Date

Earliest Anticipated Award Date: April 1, 2006.

VI. Award Administration Information

1. Award Notices

Division of Grants Operations (DGO) will not award a grant without an approved application in conformance with regulatory and policy requirements which describes the purpose and scope of the project to be funded. When the application is approved for funding, the DGO will prepare a Notice of Award (NoA) with special terms and conditions binding upon the award and refer to all general terms applicable to the award. The NoA will serve as the official notification of a grant award and will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period, and the budget period. Any other correspondence announcing to the Project Director that an application was selected is not an authorization to begin performance.

2. Administrative and National Policy Requirements

Grants are administered in accordance with the following documents

VII. Agency Contact(s)

1. Questions on the programmatic and technical issues may be directed to: Mary E. Trujillo, Program Specialist, Telephone No.: 301-443-7821. Fax No.: 301-443-1050. E-mail: metrujil@hqe.ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Patricia Spotted Horse, Grants Management Specialist, Telephone No.: 301-443-5204. Fax No.: 301-443-9602. E-mail: pspotted@hqe.ihs.gov.

VIII. Other Information

The Public Health Service (PHS) strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Dated: December 7, 2005.

Robert G. McSwain,

Deputy Director, Indian Health Service.

[FR Doc. E5-7280 Filed 12-13-05; 8:45 am]

BILLING CODE 4160-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Clinical Center; Notice of Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for discussion of personal qualifications and performance, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Advisory Board for Clinical Research.

Date: January 30, 2006.

Open: 10 a.m. to 1:30 p.m.

To review the Clinical Center operating plan, ABCR workgroups and Budgetary issues.

National Institutes of Health, Building 10, 10 Center Drive, 4-2551, CRC Medical Board Room, Bethesda, MD 20892.

Closed: 1:30 p.m. to 2 p.m.

Agenda: To review and evaluate for discussion of personal qualifications and performance the disclosure of which constitute a clearly unwarranted invasion of privacy.

Place: National Institutes of Health, Building 10, 10 Center Drive, 4-2551, CRC Medical Board Room, Bethesda, MD 20892.

Contact Person: Maureen E. Gormley, Executive Secretary, Mark O. Hatfield Clinical Research Center, National Institutes of Health, Building 10, Room 6-15610, Bethesda MD 20892, 301/496-2897.