

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**).

II. Paperwork Reduction Act of 1995

This final guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0571.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and 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

Persons with access to the Internet may obtain the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: December 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Opportunity Number: HHS-2006-IHS-TSGP-0001; CFDA Number: 93.210]

Tribal Self-Governance Program Planning Cooperative Agreement; New Funding Cycle for Fiscal Year 2006

Key Dates: Applications Due—January 20, 2006; Objective Review Committee to Evaluate Applications—March 8-9, 2006; Anticipated Project Start Date—April 1, 2006.

I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide planning resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93-638, as amended. The TSGP is designed to promote self-determination by allowing Tribes to assume more control of Indian Health Service (IHS) programs and services through compacts negotiated with the IHS. The Planning Cooperative