

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[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; Addendum December 30, 2005; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) published a notice in the **Federal Register** of December 14, 2005 (70 FR 74020) 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 guidance document provided 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 for the *trans* fat labeling final rule, of some or all existing label stock that does not declare *trans* fat labeling in compliance with the final rule. This is to notify all interested persons of an addendum to that guidance.

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 the guidance document 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. Include a self-addressed adhesive label to assist that office in processing your request. 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>. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. 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 announced the availability of a guidance document for industry and FDA entitled, “Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006,” in the **Federal Register** of December 14, 2005 (70 FR 74020). Based on the number of requests the agency received asking it to consider enforcement discretion, FDA decided to incorporate an addendum into that guidance. Thus, FDA is issuing this notice to inform all interested persons of the addendum to that guidance.

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.

4

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: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S