

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0169]

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Docket No. 5/1/06
5/2/06
J. O. Ke

Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under the Federal Food, Drug, and Cosmetic Act; 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 "Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under the Federal Food, Drug, and Cosmetic Act" (the act). The guidance explains FDA's current thinking on the labeling of certain uses of lecithin derived from soy under the act. This guidance is part of FDA's implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA).

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Additive Safety (HFS-205), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1200, FAX: 301-436-2972. Send one self-addressed adhesive label to assist the 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>. 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: Paul M. Kuznesof, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1289, or e-mail:

paul.kuznesof@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled "Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act." This guidance is part of FDA's implementation of FALCPA (Public Law 108-282). If a food is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains a major food allergen, the food must comply with section 403(w) of the act (21 U.S.C. 343(w)). Section 403(w)(1) requires that the food's label declare the name of the food source from which the major food allergen is derived in a manner specified by that section. This source declaration requirement is extended by section 403(w)(4) to any incidental additive that is, or that bears or contains, a major food allergen, notwithstanding the regulatory exemption for incidental additives in 21 CFR 101.100(a)(3). The requirements of section 403(w) of the act apply to foods labeled on or after January 1, 2006.

II. Discussion

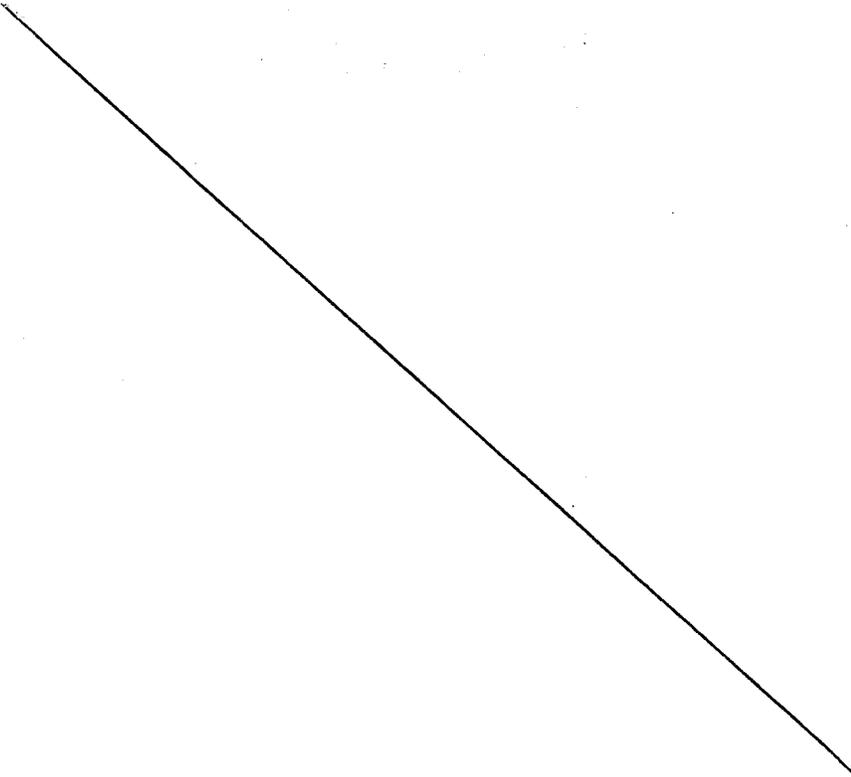
The purpose of the guidance document is to provide guidance to the industry on the labeling, under section 403(w) of the act, of certain uses of lecithin derived from soy in packaged foods. In particular, as discussed in the guidance, FDA intends to consider the exercise of enforcement discretion for a packaged food labeled on or after January 1, 2006, in which lecithin derived from soy is used solely as a component of a release agent and the label for such food does not declare the presence of the lecithin consistent with the requirements of section 403(w). FDA intends to consider exercising such discretion when all of the factors discussed in the guidance are present.

FDA is issuing this guidance as 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. As noted, foods labeled on or after January 1, 2006, must comply with section 403(w) of the act's labeling requirements.

This guidance represents the agency's current thinking on the labeling of certain uses of lecithin derived from soy under section 403(w) of the act. 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**).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance 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

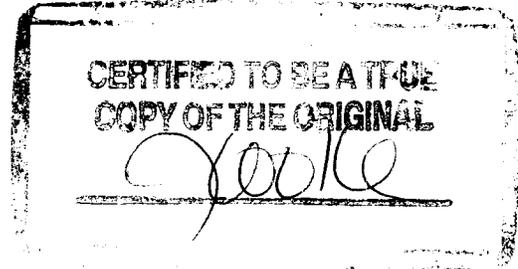
Persons with access to the Internet may obtain the guidance document at
<http://www.cfsan.fda.gov/guidance.html>.

Dated: _____

4/25/06
April 25, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.



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