DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0490]

Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance document entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2).'' The guidance explains, using a question and answer format, FDA's current thinking on a number of issues related to the regulation of food allergens, including implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA).

DATES: Submit written or electronic comments on the guidance document at any time.

ADDRESSES: 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: Rhonda R. Kane, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371, or e-mail: *rhonda.kane@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The FALCPA (Public Law 108–282) amends the Federal Food, Drug, and Cosmetic Act and requires that the label of a food product that is or contains an ingredient that bears or contains a ''major food allergen'' declare the presence of the allergen as specified by FALCPA. FALCPA defines a ''major food allergen'' as one of eight foods or a food ingredient that contains protein derived from one of those foods. A food ingredient may be exempt from FALCPA's labeling requirements if it does not cause an allergic response that poses a risk to human health or if it does not contain allergenic protein. FALPCA's labeling requirements apply to products labeled on or after January 1, 2006.

II. Discussion

FDA has received numerous questions about the application of FALCPA's requirements to food products. To explain FALCPA's requirements as well as FDA's current thinking on several issues relating to the regulation of food allergens, on October 5, 2005, FDA posted the first edition of a guidance entitled ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004'' on the agency's Web site at *http://www.cfsan.fda.gov/~dms/alrguid.html*. The guidance that is the subject of this notice, ''Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2)'' is a revision of the guidance posted on October 5, 2005, and responds to additional questions about FALCPA and food allergens. The revised guidance is intended to share with industry FDA's current thinking on the additional questions presented in the guidance.

Given the nature of the revisions to the guidance, FDA is issuing the guidance as a level 1 guidance. Consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)), the agency will accept comments, but it 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, FALPCA's labeling requirements apply to products labeled on or after January 1, 2006. Clarifying FDA's current thinking on the additional issues presented by FALCPA's implementation will help facilitate the food industry's compliance with FALCPA's requirements.

FDA expects to continue to receive a large number of questions regarding the implementation of FALCPA and the regulation of food allergens generally. The agency intends to respond to these inquires under § 10.115 as promptly as possible, using a question and answer format. The agency believes that, at the present time, it is reasonable to maintain all responses to questions concerning food allergens and FALCPA in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

This guidance represents the agency's current thinking on issues related to FALCPA and food allergens generally that are presented in the guidance. The guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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.

V. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/~dms/alrguid2.html*. Other information about food allergens may be obtained at *http://www.cfsan.fda.gov/~dms/wh-alrgy.html*.

Dated: December 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR