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FDA Releases a Revised Guidance for Industry and an Advice to Consumers Document Regarding Food Allergens

FDA recently released a revised final "Guidance for Industry" document entitled "Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2)" [1] and a new document entitled "Advice to Consumers: Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers." [2] These documents together represent FDA's current thinking with respect to key compliance issues presented for food companies under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) [3], which imposes new allergen labeling requirements for foods labeled on or after January 1, 2006.

FALCPA requires that uniform, plain English terminology be used in ingredient labeling to declare the presence of eight major food allergens, defined as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. The recent FDA guidance elaborates upon FALCPA's statutory requirements and clarifies how FDA will interpret key provisions for compliance purposes. Covington & Burling welcomes inquiries related to these or other food labeling issues, and is pleased to provide counsel on FALCPA compliance.

I. Exclusions from FALCPA Labeling Requirements

The FDA guidance clarifies that the following types of food products are not subject to FALCPA's labeling requirements:

- food products **labeled before January 1, 2006** (FDA states that FALCPA does not require any action with respect to products labeled before January 1, 2006; FDA cautions consumers that there will be "a transition period of undetermined length" after January 1 during which consumers may see packaged food on store shelves without FALCPA–compliant labeling);

- food products that are not intended to contain major allergens but inadvertently contain allergen residues due to "cross-contact";

- restaurant foods that are unpackaged or placed in a wrapper or container in response to a consumer's order; and

- meat products, poultry products, and egg products regulated by the U.S. Department of Agriculture.

FDA also announces that it has made available on the Internet a list of the notifications for exemptions of ingredients from FALCPA's labeling requirements that FDA receives (http://www.cfsan.fda.gov/~dms/falnoti.html). As of December 7, 2005, FDA had received requests for the exemption of extensively hydrolyzed casein (source allergen: milk) and a starter growth media (source allergen: soy).

[1] This guidance is available at http://www.cfsan.fda.gov/~dms/alrguid2.html (issued December 14, 2005). This document updates the earlier final "Guidance for Industry" document issued on October 5, 2005. The new revised guidance is expanded to include Question 18, which addresses labeling of food products that unintentionally contain allergens due to "cross-contact" with allergens during the growing and harvesting of crops or the use of shared storage, transportation, or production equipment.

[2] This guidance is available at http://www.cfsan.fda.gov/~dms/alrgqa.html (issued December 12, 2005).

[3] Public Law 108-282, Title II, available at http://www.cfsan.fda.gov/~dms/alrgact.html.

II. Format for FALCPA Labeling

FDA elaborates on acceptable formats for allergen disclosure:

▪ if the manufacturer chooses to declare major allergens in a "contains" statement, the statement must include the names of all major allergens present in a food, whether or not the name of the allergen is already clearly stated in the ingredient list (note: an example provided in Question 10 of the Advice to Consumers document inadvertently fails to apply this principle which FDA stated in Question 13 in the Guidance for Industry);

▪ a "Contains" statement may be worded in a variety of ways, so long as: (1) the word "Contains" (with a capital "C") is the first word to begin the statement; (2) the names used to declare the food sources of the major allergens are those allowed by FALCPA and FDA guidance; and (3) the statement identifies the names of the food sources for all major food allergens that are contained in the food;

▪ the terms "soybean," "soy," or "soya" may be used to identify the food source of the allergen "soybeans"; and

▪ singular terms such as "peanut," "almond," and "pecan" may be used to identify the presence of peanuts or tree nuts.

III. Major Allergen Thresholds

Allergen labeling is not required under FALCPA when the allergenic protein of a major food allergen is present at a level that FDA has determined will not cause allergic reactions. The Advice to Consumers guidance notes that a Food Advisory Committee Meeting held in June 2005 evaluated FDA's draft report, "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." The report discusses currently available approaches to establish thresholds and concludes that any approach used to establish a threshold should be re-examined periodically to consider new knowledge, data, and approaches. The report and FDA guidance indicate that FDA may evaluate possible thresholds in the future, which may result in certain minute quantities of allergenic protein being exempt from FALCPA's disclosure requirements.

IV. Criteria to Define "Gluten-Free"

In the Advice to Consumers guidance, FDA provides a link to the transcript of an August 2005 Public Meeting on Gluten-Free Food Labeling. FDA explains that the agency will use information it gained from the Public Meeting and the Food Advisory Committee Meeting to develop a proposed rule to permit the voluntary use of the term "gluten-free." FALCPA requires FDA to issue a final rule by August 2008.

V. Legal Risk Management Issues

In the recent Guidance for Industry, FDA cautions that companies failing to comply with FALCPA requirements may be subject to civil sanctions and/or criminal penalties under the Federal Food, Drug, and Cosmetic Act.

FDA will likely continue to address questions related to allergen labeling as FALCPA's provisions go into effect, companies seek exemptions from FALCPA's labeling scheme for certain ingredients, and FDA establishes a standard for the term "gluten- free." For food companies, allergen labeling involves considerations of both regulatory enforcement risks and consumer litigation risks, which are likely to be particular to each company. Covington & Burling is experienced in these matters and is available to provide individualized legal risk management counseling with respect to allergen labeling and allergen management.

Covington & Burling plays a leading role in life sciences law, both in the United States and throughout the world. Our life sciences practice reflects the firm's overall strength in the area of food and drug law, including government regulation, litigation, transactional work, intellectual property and high technology. With offices in Washington, New York, London, Brussels and San Francisco, Covington & Burling has broad experience in dealing with every facet of the regulation of food, pharmaceuticals and biotechnology products.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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