ATTACHMENT-8

U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

August 2, 2004

Food Allergen Labeling and Consumer Protection Act of 2004
(Title II of Public Law 108-282)

(This document also available in PDF)

SEC. 201. SHORT TITLE.

Food Allergen Labeling and Consumer Protection Act of 2004. 21 USC 301 note.

This title may be cited as the ``Food Allergen Labeling and Consumer Protection Act of 2004".

SEC. 202. FINDINGS.

21 USC 343 note.

Congress finds that--

(1) it is estimated that--
(A) approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies; and
(B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;

(2)
(A) eight major foods or food groups--milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans-- account for 90 percent of food allergies;
(B) at present, there is no cure for food allergies; and
(C) a food allergic consumer must avoid the food to which the consumer is allergic;

(3)
(A) in a review of the foods of randomly selected manufacturers of baked goods, ice cream, and candy in Minnesota and Wisconsin in 1999, the Food and Drug Administration found that 25 percent of sampled foods failed to list peanuts or eggs as ingredients on the food labels; and
(B) nationally, the number of recalls because of unlabeled allergens rose to 121 in 2000 from about 35 a decade earlier;

(4) a recent study shows that many parents of children with a food allergy were unable to correctly identify in each of several food labels the ingredients derived from major food allergens;

(5)
(A) ingredients in foods must be listed by their ``common or usual name";
(B) in some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen; and

(C) in other cases, the ingredients may be declared as a class, including spices, flavorings, and certain colorings, or are exempt from the ingredient labeling requirements, such as incidental additives; and

(6)

(A) celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs;
(B) the current recommended treatment is avoidance of glutens in foods that are associated with celiac disease; and
(C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population.

SEC. 203. FOOD LABELING; REQUIREMENT OF INFORMATION REGARDING ALLERGENIC SUBSTANCES.

(a) In General.--Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

``(w)

(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either--

``(A) the word `Contains', followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or
``(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when--

``(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or
``(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

``(2) As used in this subsection, the term `name of the food source from which the major food allergen is derived' means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term `name of the food source from which the major food allergen is derived' means the name of the specific type of nut or species of fish or Crustacean shellfish.

``(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other

Federal Register, publication.

labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

``(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

``(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

``(6)

(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

``(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

``(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

``(D) A determination regarding a petition under this paragraph shall constitute final agency action.

Public information. Deadline.

``(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

``(7)

(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing--

``(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

``(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

Deadlines.

``(B) The food ingredient may be introduced or delivered for introduction into interstate

commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

``(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

Public information. Deadline.

``(x) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.".

21 USC 343 note.

(b) Effect on Other Authority.--The amendments made by this section that require a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to require a label or labeling for other food allergens.

(c) Conforming Amendments.--

(1) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) (as amended by section 102(b)) is amended by adding at the end the following:

``(qq) The term `major food allergen' means any of the following:

``(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

``(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

``(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

``(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).".

(2) Section 403A(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(2)) is amended by striking ``or 403(i)(2)" and inserting ``403(i)(2), 403 (w), or 403(x)".

(d) Effective Date.--The amendments made by this section shall apply to any food that is labeled on or after January 1, 2006.

Applicability. 21 USC 321 note.

SEC. 204. REPORT ON FOOD ALLERGENS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ``Secretary") shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that--

(1)
(A) analyzes--
(i) the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens, including contamination caused by the use by manufacturers of the same production line to produce both products for which major food allergens are intentional ingredients and products for which major food allergens are not intentional ingredients; and
(ii) the ways in which foods produced on dedicated production lines are unintentionally contaminated with major food allergens; and
(B) estimates how common the practices described in subparagraph (A) are in the food industry, with breakdowns by food type as appropriate;
(2) advises whether good manufacturing practices or other methods can be used to reduce or eliminate cross-contact of foods with the major food allergens;
(3) describes--
(A) the various types of advisory labeling (such as labeling that uses the words ``may contain") used by food producers;
(B) the conditions of manufacture of food that are associated with the various types of advisory labeling; and
(C) the extent to which advisory labels are being used on food products;
(4) describes how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms;
(5) states the number of inspections of food manufacturing and processing facilities conducted in the previous 2 years and describes--
(A) the number of facilities and food labels that were found to be in compliance or out of compliance with respect to cross-contact of foods with residues of major food allergens and the proper labeling of major food allergens;
(B) the nature of the violations found; and
(C) the number of voluntary recalls, and their classifications, of foods containing undeclared major food allergens; and
(6) assesses the extent to which the Secretary and the food industry have effectively addressed cross-contact issues.

SEC. 205. INSPECTIONS RELATING TO FOOD ALLERGENS.

21 USC 374a.

The Secretary of Health and Human Services shall conduct inspections consistent with the authority under section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) of facilities in which foods are manufactured, processed, packed, or held--

(1) to ensure that the entities operating the facilities comply with practices to reduce or

eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food; and
(2) to ensure that major food allergens are properly labeled on foods.

SEC. 206. GLUTEN LABELING.

Deadlines. Regulations. 21 USC 343 note.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term ``gluten-free" on the labeling of foods. Not later than 4 years after the date of enactment of this Act, the Secretary shall issue a final rule to define, and permit use of, the term ``gluten-free" on the labeling of foods.

SEC. 207. IMPROVEMENT AND PUBLICATION OF DATA ON FOOD-RELATED ALLERGIC RESPONSES.

42 USC 242r.

(a) In General.--The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) the collection of, and publish as it becomes available, national data on--
(1) the prevalence of food allergies;
(2) the incidence of clinically significant or serious adverse events related to food allergies; and
(3) the use of different modes of treatment for and prevention of allergic responses to foods.
(b) Authorization of Appropriations.--For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 208. FOOD ALLERGIES RESEARCH.

42 USC 243 note.

Government organization.

(a) In General.--The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene an ad hoc panel of nationally recognized experts in allergy and immunology to review current basic and clinical research efforts related to food allergies.

Deadline. Public information.

(b) Recommendations.--Not later than 1 year after the date of enactment of this Act, the panel shall make recommendations to the Secretary for enhancing and coordinating research activities concerning food allergies, which the Secretary shall make public.

SEC. 209. FOOD ALLERGENS IN THE FOOD CODE.

The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private

entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.

SEC. 210. RECOMMENDATIONS REGARDING RESPONDING TO FOOD-RELATED ALLERGIC RESPONSES.

42 USC 300d-2 note.

The Secretary of Health and Human Services shall, in providing technical assistance relating to trauma care and emergency medical services to State and local agencies under section 1202(b)(3) of the Public Health Service Act (42 U.S.C. 300d-2(b)(3)), include technical assistance relating to the use of different modes of treatment for and prevention of allergic responses to foods.

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U.S. Food and Drug Administration

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FDA to Require Food Manufacturers to List Food Allergens

Consumers with Allergies Will Benefit From Improved Food Labels

Effective January 1, 2006, the Food and Drug Administration (FDA) is requiring food labels to clearly state if food products contain any ingredients that contain protein derived from the eight major allergenic foods. As a result of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), manufacturers are required to identify in plain English the presence of ingredients that contain protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybeans in the list of ingredients or to say "contains" followed by name of the source of the food allergen after or adjacent to the list of ingredients.

"I applaud Congress for the passage of FALCPA," said Andrew C. von Eschenbach, M.D., Acting FDA Commissioner. "Chairman Joe Barton and Ranking Member John D. Dingell in the House, Energy and Commerce Committee were instrumental in moving this bipartisan legislation forward. Representative Nita Lowey was the original sponsor of the legislation. FDA also applauds the dedication and leadership of the legislation's sponsors in the Senate, which include Senators Judd Gregg and Edward Kennedy."

This labeling will be especially helpful to children who must learn to recognize the presence of substances they must avoid. For example, if a product contains the milk-derived protein, casein, the product's label will have to use the term "milk" in addition to the term "casein" so that those with milk allergies can clearly understand the presence of the allergen they need to avoid.

It is estimated that 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies. Approximately 30,000 consumers require emergency room treatment and 150 Americans die each year because of allergic reactions to food.

"The eight major food allergens account for 90 percent of all documented food allergic reactions, and some reactions may be severe or life-threatening," said Robert E. Brackett, PhD, Director of FDA's Center for Food Safety and Applied Nutrition. "Consumers will benefit from improved food labels for products that contain food allergens."

FALCPA does not require food manufacturers or retailers to relabel or remove from grocery or supermarket shelves products that do not reflect the additional allergen labeling as long as the products were labeled before the effective date. As a result, FDA cautions consumers that there will be a transition period of undetermined length during which it is likely that consumers will see packaged food on store shelves and in consumers' homes without the revised allergen labeling.

For more information about FALCPA, visit FDA's food allergy page at

http://www.cfsan.fda.gov/~dms/wh-alrgy.html.

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