107TH CONGRESS
2D SESSION

# S. 2499

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling requirements regarding allergenic substances in food, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

MAY 9, 2002

Mr. KENNEDY (for himself and Mrs. CLINTON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling requirements regarding allergenic substances in food, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Food Allergen Consumer Protection Act''.

**SEC. 2. FINDINGS.**

The Congress finds as follows:

(1) Approximately 7,000,000 Americans suffer from food allergies. Every year roughly 30,000 peo-

ple receive emergency room treatment due to the ingestion of allergenic foods, and an estimated 150 Americans die from anaphylactic shock caused by a food allergy.

(2) Eight major foods—milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soybeans—cause 90 percent of allergic reactions. At present, there is no cure for food allergies. A food allergic consumer depends on a product's label to obtain accurate and reliable ingredient information so as to avoid food allergens.

(3) Current Food and Drug Administration regulations exempt spices, flavorings, and certain colorings and additives from ingredient labeling requirements that would allow consumers to avoid those to which they are allergic. Such unlabeled food allergens may pose a serious health threat to those susceptible to food allergies.

(4) A recent Food and Drug Administration study found that 25 percent of bakery products, ice creams, and candies that were inspected failed to list peanuts and eggs, which can cause potentially fatal allergic reactions. The mislabeling of foods puts those with a food allergy at constant risk.

(5) In that study, the Food and Drug Administration found that only slightly more than half of inspected manufacturers checked their products to ensure that all ingredients were accurately reflected on the labels. Furthermore, the number of recalls because of unlabeled allergens rose to 121 in 2000 from about 35 a decade earlier. In part, mislabeling occurs because potentially fatal allergens are introduced into the manufacturing process when production lines and cooking utensils are shared or used to produce multiple products.

(6) Individuals who have food allergies may outgrow their allergy if they strictly avoid consuming the allergen. However, some scientists believe that because low levels of allergens are unintentionally present in foods, those with an allergy are unable to keep from being repeatedly exposed to the very foods they are allergic to. Good manufacturing practices can minimize the unintentional presence of food allergens. In addition, when good manufacturing practices cannot eliminate the potential for cross-contamination, an advisory label on the product can provide additional consumer protection.

(7) The Food and Drug Administration is the Nation's principal consumer protection agency,

charged with protecting and promoting public health through premarket and postmarket regulation of food. The agency must have both the necessary authority to ensure that foods are properly labeled and produced using good manufacturing practices and the ability to penalize manufacturers who violate our food safety laws.

(8) Americans deserve to have confidence in the safety and labeling of the food on their tables.

**SEC. 3. 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:

''(t)(1) If it is not a raw agricultural commodity and it is, or it intentionally bears or contains, a known food allergen, unless its label bears, in bold face type, the common or usual name of the known food allergen and the common or usual name of the food source described in subparagraph (3)(A) from which the known food allergen is derived, except that the name of the food source is not required when the common or usual name of the known food allergen plainly identifies the food source.

''(2) The information required under this paragraph may appear in labeling other than the label only if the

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

''(3) For purposes of this Act, the term 'known food allergen' means any of the following:

''(A) Milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soybeans.

''(B) A proteinaceous substance derived from a food specified in clause (A), unless the Secretary determines that the substance does not cause an allergic response that poses a risk to human health.

''(C) Other grains containing gluten (rye, barley, oats, and triticale).

''(D) In addition, any food that the Secretary by regulation determines causes an allergic or other adverse response that poses a risk to human health.

''(4) Notwithstanding paragraph (g), (i), or (k), or any other law, the labeling requirement under this paragraph applies to spices, flavorings, colorings, or incidental additives that are, or that bear or contain, a known food allergen.

''(u) If it is a raw agricultural commodity that is, or bears or contains, a known food allergen, unless it has

a label or other labeling that bears in bold face type the common or usual name of the known food allergen and the Secretary has found that the label or other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph is effective upon publication in the Federal Register as a notice (including any change in an earlier finding under this paragraph).

''(w) If the labeling required under paragraphs (g), (i), (k), (t), (u), or (v)—

''(1) does not use a single, easy-to-read type style that is black on a white background, using upper and lower case letters and with no letters touching;

''(2) does not use at least 8 point type with at least one point leading (i.e., space between two lines of text), provided the total surface area of the food package available to bear labeling exceeds 12 square inches; or

''(3) does not comply with regulations issued by the Secretary to make it easy for consumers to read and use such labeling by requiring a format that is comparable to the format required for the disclosure of nutrition information in the food label under section 101.9(d)(1) of title 21, Code of Federal Regulations.''.

(b) CIVIL PENALTIES.—Section 303(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)(2)) is amended—

(1) in subparagraph (A), by striking ''section 402(a)(2)(B) shall be subject'' and inserting the following: ''section 402(a)(2)(B) or regulations under this chapter to minimize the unintended presence of allergens in food, or that is misbranded within the meaning of section 403(t), 403(u), 403(v), or 403(w), shall be subject''; and

(2) in subparagraph (B), by inserting ''or misbranded'' after ''adulterated'' each place such term appears.

(c) CONFORMING AMENDMENT.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ll) The term 'known food allergen' has the meaning given such term in section 403(t)(3).''.

(d) EFFECTIVE DATE.—The amendments made by this section take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act.

**SEC. 4. UNINTENTIONAL PRESENCE OF KNOWN FOOD ALLERGENS.**

(a) FOOD LABELING OF SUCH FOOD ALLERGENS.—Section 403 of the Federal Food, Drug, and Cosmetic Act,

as amended by section 3(a) of this Act, is amended by inserting after paragraph (u) the following:

''(v) If the presence of a known food allergen in the food is unintentional and its labeling bears a statement that the food may bear or contain the known food allergen, or any similar statement, unless the statement is made in compliance with regulations issued by the Secretary to provide for advisory labeling of the known food allergen.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect upon the expiration of the four-year period beginning on the date of the enactment of this Act, except with respect to the authority of the Secretary of Health and Human Services to engage in rulemaking in accordance with section 5.

**SEC. 5. REGULATIONS.**

(a) IN GENERAL.—

(1) REGULATIONS.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall issue a proposed rule under sections 402, 403, and 701(a) of the Federal Food, Drug, and Cosmetic Act to implement the amendments made by this Act. Not later than two years after such date of enactment,

the Secretary shall promulgate a final rule under such sections.

(2) EFFECTIVE DATE.—The final rule promulgated under paragraph (1) takes effect upon the expiration of the four-year period beginning on the date of the enactment of this Act. If a final rule under such paragraph has not been promulgated as of the expiration of such period, then upon such expiration the proposed rule under such paragraph takes effect as if the proposed rule were a final rule.

(b) UNINTENTIONAL PRESENCE OF KNOWN FOOD ALLERGENS.—

(1) GOOD MANUFACTURING PRACTICES; RECORDS.—Regulations under subsection (a) shall require the use of good manufacturing practices to minimize, to the extent practicable, the unintentional presence of allergens in food. Such regulations shall include appropriate record keeping and record inspection requirements.

(2) ADVISORY LABELING.—In the regulations under subsection (a), the Secretary shall authorize the use of advisory labeling for a known food allergen when the Secretary has determined that good manufacturing practices required under the regulations will not eliminate the unintentional presence of

the known food allergen and its presence in the food poses a risk to human health, and the regulations shall otherwise prohibit the use of such labeling.

(c) INGREDIENT LABELING GENERALLY.—In regulations under subsection (a), the Secretary shall prescribe a format for labeling, as provided for under section 403(w)(3) of the Federal, Food, Drug, and Cosmetic Act.

(d) REVIEW BY OFFICE OF MANAGEMENT AND BUDGET.—If the Office of Management and Budget (in this section referred to as ''OMB'') is to review proposed or final rules under this Act, OMB shall complete its review in 10 working days, after which the rule shall be published immediately in the Federal Register. If OMB fails to complete its review of either the proposed rule or the final rule in 10 working days, the Secretary shall provide the rule to the Office of the Federal Register, which shall publish the rule, and it shall have full effect (subject to applicable effective dates specified in this Act) without review by OMB. If the Secretary does not complete the proposed or final rule so as to provide OMB with 10 working days to review the rule and have it published in the Federal Register within the time frames for publication of the rule specified in this section, the rule shall be published without review by OMB.

**SEC. 6. FOOD LABELING; INCLUSION OF TELEPHONE NUMBER.**

(a) IN GENERAL.—Section 403(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(e)) is amended—

(1) by striking ''and (2)'' and inserting the following: ''(2) in the case of a manufacturer, packer, or distributor whose annual gross sales made or business done in sales to consumers equals or exceeds $500,000, a toll-free telephone number (staffed during reasonable business hours) for the manufacturer, packer, or distributor (including one to accommodate telecommunications devices for deaf persons, commonly known as TDDs); or in the case of a manufacturer, packer, or distributor whose annual gross sales made or business done in sales are less than $500,000, the mailing address or the address of the Internet site for the manufacturer, packer, or distributor; and (3)''; and

(2) by striking ''clause (2)'' and inserting ''clause (3)''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act.

**SEC. 7. DATA ON FOOD-RELATED ALLERGIC RESPONSES.**

(a) IN GENERAL.—Consistent with the findings of the study conducted under subsection (b), the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Foods and Drugs, shall improve the collection of, and (beginning 18 months after the date of the enactment of this Act) annually publish, national data on—

(1) the prevalence of food allergies, and

(2) the incidence of deaths, injuries, including anaphylactic shock, hospitalizations, and physician visits, and the utilization of drugs, associated with allergic responses to foods.

(b) STUDY.—Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with consumers, providers, State governments, and other relevant parties, shall complete a study for the purposes of—

(1) determining whether existing systems for the reporting, collection and analysis of national data accurately capture information on the subjects specified in subsection (a); and

(2) identifying new or alternative systems, or enhancements to existing systems, for the reporting

collection and analysis of national data necessary to fulfill the purpose of subsection (a).

(c) PUBLIC AND PROVIDER EDUCATION.—The Secretary shall, directly or through contracts with public or private entities, educate physicians and other health providers to improve the reporting, collection, and analysis of data on the subjects specified in subsection (a).

(d) CHILD FATALITY REVIEW TEAMS.—Insofar as is practicable, activities developed or expanded under this section shall include utilization of child fatality review teams in identifying and assessing child deaths associated with allergic responses to foods.

(e) REPORTS TO CONGRESS.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Congress a report on the progress made with respect to subsections (a) through (d).

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 2003, and such sums as may be necessary for each subsequent fiscal year.

(g) EFFECTIVE DATE.—This section takes effect on the date of the enactment of this Act.

**SEC. 8. FOOD ALLERGIES RESEARCH.**

(a) IN GENERAL.—The Secretary of Health and Human Services, through the National Institutes of Health, shall convene a panel of nationally recognized experts to review current basic and clinical research efforts related to food allergies. The panel shall develop a plan, including recommendations for expenditures, for expanding, intensifying, and coordinating research activities concerning food allergies.

(b) REPORT TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a plan under subsection (a) to the Committee on Energy and Commerce in the House of Representatives and the Committee on Health, Education, Labor, and Pensions in the Senate.

(c) EFFECTIVE DATE.—This section takes effect on the date of the enactment of this Act.

**SEC. 9. CERTAIN FEDERAL RECOMMENDATIONS REGARDING AVOIDING AND RESPONDING TO FOOD-RELATED ALLERGIC RESPONSES.**

The Secretary of Health and Human Services shall carry out the following:

(1) Develop and appropriately disseminate recommendations on—

(A) training emergency medical technicians with respect to administering epinephrine auto-injector devices; and

(B) the need for emergency vehicles to maintain supplies of such devices.

(2) Activities to increase the awareness by the restaurant industry of public or private guidelines and recommendations for training in preparing allergen-free foods, including the Food Allergy and Anaphylaxis Network and Food Allergy Initiative's document entitled ''Food Allergy Training Guide for Restaurants and Good Services''.

(3) With respect to food prepared for students by elementary and secondary schools, develop and appropriately disseminate recommendations for the preparation of allergen-free foods, with priority given to the issue of life-threatening food allergies.

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