CSPI Center for Science in the Public Interest

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April 19, 2001

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
Room 615F
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Att: Mary Kay Mantho

Dear Secretary Thompson:

On behalf of our 800,000 members, I write to urge that the Food and Drug Administration take immediate action to protect the seven million Americans who suffer from food allergies. Each year 30,000 people are rushed to emergency rooms because of anaphylactic shock from eating the wrong food, and about 150 of them die.

Several years ago, the FDA asked the food industry to voluntarily improve its labeling and reform its manufacturing practices. In June 1996, Dr. Fred R. Shank, then Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), wrote to the National Food Processors Association (NFPA) and more than 100 other food trade associations asking them to notify their members of the need to voluntarily disclose on the package even minute amounts of allergens (including those in spices, flavorings, and colorings) and "to take all steps necessary to eliminate cross contamination." In December 1996, Dr. David A. Kessler, then FDA Commissioner, also wrote to the NFPA asking for its help in "addressing a major public health problem of undeclared allergens in food." I enclose copies of both these letters.

On May 26, 2000, New York Attorney General Eliot Spitzer, along with the Attorneys General of eight other States, filed a petition with the FDA asking that it amend its regulations to: (1) close "loopholes" in FDA's food-labeling requirements, (2) require manufacturers to take all reasonable measures to prevent cross-contamination, and (3) require manufacturers to provide a toll-free number so that consumers could get more information about possible allergens. The following month, the Center for Science in the Public Interest, Public Citizen Health Research Group, Peanut Allergy.Com, and the Gluten Intolerance Group of North America wrote to Dr. Jane E. Henney, then FDA Commissioner, supporting the petition and urging the FDA "to act

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expeditiously." According to Attorney General Spitzer, the FDA has not taken action on the petition.

Meanwhile, three recent studies indicate that the food industry is not voluntarily taking the steps necessary to protect consumers.

* A 2000 survey by the FDA, Minnesota Department of Agriculture, and Wisconsin Department of Agriculture, Trade, and Consumer Protection found that in a sample of 85 manufacturers of bakery products, candy, and ice cream in Minnesota and Wisconsin, one-quarter made products that were contaminated with peanut or egg ingredients that were not declared on the product labels. (See *The New York Times,* April 3, 2001; enclosed.)

* In 1999, the Oregon Department of Agriculture tested 62 chocolate candies manufactured in Oregon that were not supposed to contain peanuts and found that 23 percent tested positive for significant levels of peanut allergens.

* In 2000, researchers at the University of Nebraska purchased from local grocery stores 19 packaged foods that neither listed peanuts as an ingredient nor warned consumers that the product may contain peanuts, and 21 percent contained detectable levels of peanut allergens.

Almost seven months after the FDA-Minnesota-Wisconsin study was completed and six days after its results were made public in the current issue of our *Nutrition Action Healthletter* (see enclosed issue at page 12), Dennis B. Baker, Associate Commissioner for Regulatory Affairs, and Joseph A. Levitt, Director of CFSAN, discussed the study in a March 26 letter to their colleagues and said "for the last two years [sic] the Agency has been actively involved in a process of increasing allergen awareness within the food industry." They said that this year the FDA will hold workshops with the food industry and consumers "to discuss allergen label issues and to find the best ways to improve the identification of food allergens within the ingredient list. This will include discussions of current incidental ingredient and collective naming exemptions." They went on to say that the FDA will train its investigators to help them help the industry identify manufacturing problems and will publish "a draft Food Allergen Compliance Policy Guide addressing needed industry manufacturing and labeling practices for food allergen control." They ignore the State Attorneys General petition requesting amendments to the FDA's current labeling and manufacturing regulations.

Two days after *The New York Times* story about the FDA-Minnesota-Wisconsin study, the NFPA issued a press release stating that it was releasing an industry Code of Practice for managing food allergens. The NFPA said that it had "taken more than a year" to complete the Code and that it had been developed in collaboration with the FDA and the United States Department of Agriculture (USDA), among others. The Code says that NFPA members will label the major food allergens in their ingredient declaration and use Good Manufacturing Practices and other allergen-control practices to minimize the potential for cross-contamination of the major

food allergens. The Code is silent about the request by the State Attorneys General that manufacturers give consumers a toll-free number they can call.

We fear that new commitments to voluntary action will be no more successful than previous efforts. To supplement voluntary actions, the Department should announce a coordinated action plan that would include:

- The FDA should immediately publish a proposed amendment of its labeling and good-manufacturing-practices regulations, along the lines requested by the State Attorneys General. That amendment would make it easier for both State and FDA inspectors to take action against those food manufacturers who ignore the problem of food allergens. The FDA could then hold public meetings with State officials, industry, and consumers to discuss possible changes in the proposed rule. That is the approach taken by Secretary Veneman in connection with the USDA's proposed food-safety rule for all ready-to-eat and partially heat-treated meat and poultry products. The USDA announced on February 27 (66 Fed. Reg. at 12609) that it would hold public meetings and scientific conferences during the comment period for its proposal.

- HHS should request an additional $7 million for FY 2002 to fund increased inspections, testing, and regulatory changes that are needed to protect consumers from food allergens. That funding should be in addition to President Bush's previous request for an additional $90 million for the FDA for FY 2002.

- The FDA should announce that it will seize products, pursuant to section 304 of the Federal Food, Drug, and Cosmetic Act, that are found to contain undeclared allergens.

- The FDA should revise its Model Food Code, which many State and local governments rely upon, to address the problem of allergens in restaurant food, a major source of adverse reactions. For example, restaurants should be encouraged to adopt procedures aimed at minimizing cross-contamination and to post a sign in the kitchen reminding cooks and waiters to prevent cross-contamination. Restaurant workers need to know that mistakes can be deadly.

- The Centers for Disease Control should institute an ongoing surveillance program for determining the approximate number of fatal and non-fatal cases of anaphylactic shock from food allergens, identifying the causes, recommending changes in business and consumer practices, and educating both businesspeople and consumers.

We look forward to working with you on this important public health matter.

Sincerely,

Michael F. Jacobson, Ph.D.
Executive Director

cc: Dr. Bernard Schwetz
Acting Principal Deputy Commissioner

Joseph A. Levitt
Director, Center for Food Safety and Applied Nutrition

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