

CSPI

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April 2, 2001

Dr. Bernard Schwetz
Acting Principal Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Schwetz:

As the FDA is well aware, food allergies can be life-threatening. An estimated 150 Americans die each year in the U.S. from anaphylactic reactions to food allergens, especially ones in peanuts and tree nuts.

In 1996, FDA Commissioner David Kessler urged companies to step up their efforts to prevent the cross-contamination of their products with food allergens and to ensure the accuracy of ingredient lists on labels. Unfortunately, three recent surveys show that some companies across the country are still failing to comply with the FDA's request.

- * In a 1999-2000 survey coordinated by the FDA, inspectors visited 85 candy, ice cream, and baked-goods manufacturers in Minnesota and Wisconsin. One-quarter of the firms were using raw ingredients such as nuts or artificial colors that were not listed on the labels. Less than half were employing procedures to control cross-contamination of foods with allergens. When inspectors tested 118 samples of foods they suspected of being contaminated with peanut or egg allergens, they found that 21 of the 85 companies were producing 23 products with enough peanut or egg proteins to cause an allergic reaction — but weren't warning consumers on their labels. Had the investigators studied additional allergens, such as wheat, milk, or soy, they might have identified even more foods with undeclared allergens.
- * In 1999, the Oregon Department of Agriculture tested 62 chocolate candies manufactured in that state that were not supposed to contain peanuts. Fourteen, or 23 percent, tested positive for significant levels of peanut allergens. State inspectors found that companies were not separating the production runs of their different candies or cleaning their machinery properly.
- * 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

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products may contain peanuts. Four of the 19 (21 percent) contained detectable levels of peanut allergens.*

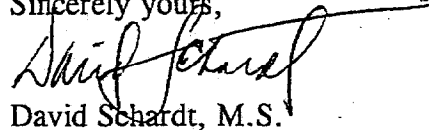
We urge the FDA to increase its efforts to protect people who suffer from food allergies. The FDA should ensure that:

- * Food labels completely and accurately list the presence of all known allergens, including those used in flavorings.
- * Food manufacturers adopt measures such as HACCP to prevent the unintentional contamination of their products with undeclared food allergens.
- * Food manufacturers include a toll-free telephone number on their labels that consumers could call for more information about ingredients.

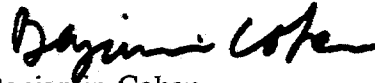
Those recommendations are included in the May 26, 2000, petition on food allergies from the Attorneys General of nine states presently before your agency. As we stated in our June 14, 2000, letter to your agency, we support that petition and urge the FDA to act upon it as soon as possible.

If the FDA believes it lacks legal authority for any of those measures, we would like to discuss where new legislation would be beneficial. Thank you for your interest in this matter.

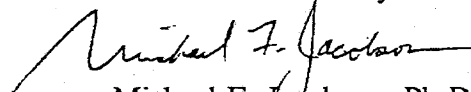
Sincerely yours,



David Schardt, M.S.
Associate Nutritionist



Benjamin Cohen
Senior Staff Attorney



Michael F. Jacobson, Ph.D.
Executive Director

* The Nebraska study also found that only six of 29 products listing peanut near the end of the ingredient statement actually contained detectable residues. Companies should not be allowed to list ingredients that are *not* intended to be present. A separate "may contain" statement would be more appropriate if a company cannot exclude the possibility of cross-contamination.