

The Food Allergy & Anaphylaxis Network (FAAN) hereby submits the following comments on CFSAN Program Priorities for FY 2006.

FAAN is a nonprofit organization whose mission is to raise public awareness, provide advocacy and education, and to advance research on behalf of all those affected by food allergies and anaphylaxis. Currently, FAAN has more than 28,000 members, the majority of whom have family members (children) who suffer from food allergies.

At the outset, FAAN acknowledges the significant accomplishments the federal government has made in the food allergy arena. An issue that received little attention just ten years ago now involves numerous federal agencies, most notably FDA/CFSAN.

For FY 2006, FAAN suggests the following priorities.

1) Increase Awareness

FDA/CFSAN must continue efforts aimed at educating consumers about food allergy. Clearly, the disease is an emerging public health and food safety issue in the US. Consider:

- Eleven million Americans (or 1 in 25 persons) suffer from food allergy: 6.5 million are allergic to seafood (i.e., lobster, crab, fish)¹, and 3.1 million are allergic to peanut or tree nut (i.e., walnuts, almonds, pecans).
- Food allergy is the leading cause of anaphylaxis outside the hospital setting, accounting for an estimated 30,000 Emergency Department visits, 2,000 hospitalizations, and 150-200 deaths each year.²
- There is no cure for food allergy. Strict avoidance of the allergen is the only way to prevent a reaction.
- Peanut allergy doubled in children from 1997 to 2002.³
- Physicians are reporting an increase in the number of food-allergic patients in the country.

2) Outreach to Industry

FDA/CFSAN must continue to provide guidance to the food industry regarding the serious nature of food allergies, avoidance of cross-contamination and the importance of accurate food ingredient labeling. Individuals affected by food

¹ Sicherer, S.H., A. Muñoz-Furlong, and H.A. Sampson. 2004. Prevalence of seafood allergy in the United States determined by a random telephone survey. *Journal of Allergy and Clinical Immunology* 114: 159-165.

² Michael W. Yocum, Joseph H. Butterfield, Joel S. Klein, Gerald W. Volcheck, Darrell R. Schroeder, and Marc D. Silverstein. Epidemiology of anaphylaxis in Olmstead County: A population-based study. *Journal of Allergy and Clinical Immunology* 1999;104:452-6.

³ Scott H. Sicherer, Anne Muñoz-Furlong, and Hugh A. Sampson. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: A 5-year follow-up study. *Journal of Allergy and Clinical Immunology* 2003;112:1203-7.

allergies rely on food labels as a first line of defense. As a result, labels must be clear, accurate, and consistent.

The results of these efforts will prove invaluable to members of the food industry, and can help reinforce that food allergy management (i.e., equipment cleaning, employee training, labeling) is a constant endeavor, and that trace amounts of an allergen can trigger a life-threatening reaction.

3) Enforce Allergen Recall Policy

FDA/CFSAN staff must take seriously, and aggressively pursue any credible consumer reports of undeclared allergens.

4) Carry Out FALCPA Provisions Related to “May Contain” Labeling

Fulfillment of these provisions will help begin the task of standardizing allergen advisory (“May Contain”) labeling, long a source of confusion for consumers affected by food allergy. Some companies use this type of labeling; others don’t; some use it sparingly, others put it on all their products. Without consistency, individuals affected by food allergy are forced to avoid the product altogether even though the product may be safe; spend more time reading and interpreting food labels; or purchase the product, placing their lives and/or the lives of their food-allergic family members at risk.

FDA/CFSAN has already begun this endeavor, through its Allergen Labeling of Food Products Consumer Preference Survey and its Experimental Study on Allergen Labeling of Food Products.

These information collection activities will provide tremendous practical utility and contribute vital data both to FDA/CFSAN and the food industry.

5) Carry out FALCPA Provisions Related to Restaurants and Schools

Restaurants and other food service establishments continue to pose a serious risk to individuals with food allergy. In a 2004 FAAN survey of individuals affected by food allergy, almost one-third of the respondents experienced a food-allergic reaction to food served in or provided by a restaurant. Restaurants and food service establishments contributed to roughly half (47%) of the fatalities reported in the 2001 fatality study, the largest of its kind to date.

There is little education and training on food allergy for restaurant staff. Complaints from consumers range from waitstaff not believing in the existence of food allergy, to restaurant managers asking patrons with food allergy to leave the establishment. With more Americans eating more meals away from home, it becomes critical that the restaurant industry address food allergy with a greater urgency.

In a survey of 400 elementary school nurses, 44% reported an increase in children with food allergies in their schools over the last 5 years; only 2% of the school nurses reported a decrease. More than one-third of the school nurses, in fact, had 10 or more students with food allergies. When asked to measure the challenge of various health issues facing elementary school children, about a third of the nurses rated food allergies on a par with other health concerns such as diabetes and learning disabilities.⁴

6) Eliminate “Non-Dairy” from Foods Containing Milk

Food products which contain “casein” (a milk derivative), but are labeled as “non-dairy” are not only misleading, but also pose a potential danger to consumers affected by milk allergy.

Many of our members have told us they have purchased “non-dairy” products for their milk-allergic children because they believed these items to be safe. Individuals often interpret “non-dairy” to mean “no dairy” and therefore do not feel it necessary to read the ingredient statement on the back of the package. In fact, doctors often advise parents of milk-allergic children to avoid “milk”, without informing the patient/parent of technical ingredient names such as casein.

However, FAAN has learned of situations in which “non-dairy” items (such as whipped toppings, imitation cheeses, and soft-serve frozen desserts) have caused milk-allergic reactions in children because it was later discovered that the item contained a milk-derived protein.

Clearly, this is a situation that no parent should have to face.

7) Report to the Public on Allergen Adverse Events

Recalls due to undeclared allergens continue to occur, with the major causes including ingredient statement omissions and errors, manufacturing equipment cross-contact, and errors by ingredient suppliers or manufacturing firm employees. Upon discovery of an undeclared allergen, the food-allergic public must be notified as soon as possible, as lives are clearly at stake.

In closing, we applaud the efforts of FDA/CFSAN. Ongoing projects will undoubtedly yield invaluable insight and help improve the lives of all those affected by food allergies. Eleven million Americans have food allergy; and they depend on the FDA/CFSAN for protection. We again urge the agency to collaborate with FAAN as the agency moves forward on these endeavors.

⁴ Christopher Weiss, Anne Munoz-Furlong, Terence J. Furlong, and Julie Arbit. Impact of Food Allergies on School Nursing Practice. *Journal of School Nursing* 2004;20:268-78.