



July 25, 2001

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food Labeling & Allergen Contamination Control

Dear Sir or Madam:

I am writing to request the opportunity to make an oral presentation at the August 13th meeting on Food Labeling & Allergen Contamination Control. The Food Allergy Initiative (FAI) and its speakers encourage the Food and Drug Administration (FDA) to regulate ingredient statements on all food products to clearly list, in plain English, any or all of the eight most common food allergens (peanuts, tree nuts, fish, shellfish, eggs, milk, soy, and wheat), contained within the product's ingredients, including spices and natural or artificial flavorings and colors. In addition, we urge the FDA to support the development and enforcement of improved food manufacturing processes so that the incidence of cross-contamination is reduced. Lastly, we encourage the FDA to require working telephone numbers on all food products.


Over seven million American children and adults suffer from food allergies. Recent studies estimate that each year over 150 Americans die due to the ingestion of allergenic foods and 30,000 receive life-saving treatment in emergency rooms. The good news is that with the government's help, many of these deaths and near-fatal incidents can be prevented. Improved ingredient labels will help save lives.

The following individuals will be participating in the presentation:

- Todd J. Slotkin, 876 Park Avenue, New York, NY 10021
- Dr. Scott Sicherer, Mount Sinai School of Medicine, One Gustave L. Levy Place, New York, NY 10029-6574
- Sara Michelle Gitlin, 27 East 93rd Street, New York, NY 10128

If you require any additional information, please do not hesitate to contact me at (212) 527-5835. We look forward to presenting on August 13, 2001.

Sincerely,


Amie Rappoport, Esq.
Administrative Director

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Facts About Anaphylaxis

Anaphylaxis is the most severe type of allergic reaction. It is sudden, severe and potentially fatal. It results when the body's immune system reacts to otherwise harmless food proteins. Anaphylactic symptoms can include:

- Hives
- Swelling of the lips, tongue and throat
- Shortness of breath, wheezing
- Nausea
- Vomiting
- Drop in blood pressure, and
- Loss of consciousness

Anaphylaxis should always be considered a medical emergency, as it may result in brain damage or death.

Food allergies are the single leading cause of anaphylaxis outside of the hospital setting.

Although any food could potentially cause anaphylaxis, the most common causes are peanut, nuts from trees, and seafood.

Epinephrine is the key medication that reverses the symptoms of anaphylaxis and should be carried by those at risk. It must be given as soon as possible to hold off symptoms, buying time to get to an emergency room for more care.

Unfortunately, epinephrine and other treatments are not fail-safe. Too many allergy sufferers succumb to food-induced anaphylaxis each year, no treatment available today could save their lives.



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When is an allergy life threatening?



When it is a food allergy.

The Food Allergy Initiative supports *research* to find a cure, *clinical activities* to identify and treat those at risk, *public policy* to make the world safer for those afflicted, and *awareness and education* to make restaurants, schools, day care centers and camps safer.

Facts About Food Allergies

A food allergy develops when the body's immune system becomes misdirected and attacks harmless food proteins.

More than 6,000,000 Americans have food allergies of varying degrees of severity – at least 8% of children less than 3 years of age and 2% of the adult population in the United States.

Food allergies affect children and adults of all races and ethnicity and can develop at any age.

Most importantly, hundreds die each year from food allergy and more than 30,000 others experience potentially life-threatening anaphylactic reactions from foods.

While any food can cause allergies, 90% of all food allergic reactions are caused by:

Egg	Peanut	Tree Nuts
Fish	Shellfish	(Walnut, pecan, etc)
Milk	Soy	Wheat

Children of parents with any type of allergy are particularly at risk. Even children without any family history of allergies can develop severe food allergies.

Food allergy can be responsible for chronic diseases such as eczema and can stunt growth in infants and children by damaging the digestive system.

There is no cure for food allergy; only strict avoidance of the allergy-causing food can prevent an allergic-reaction.



Food Allergy Initiative

The Food Allergy Initiative (FAI) is a 501(c)(3) non-profit organization which was founded to raise funds toward the effective treatment and cure for food allergies. Food allergies differ from other allergies because a minuscule amount of the wrong food can be fatal. Today, it is estimated that 6,000,000 Americans are affected by food allergies, at least 30,000 experience episodes of food-induced anaphylaxis, and hundreds die each year in the United States.

FAI is the first organization dedicated to a strategic, comprehensive, multi-disciplinary approach to food allergies. Our program is designed to help the millions of children and adults who live in fear of eating the wrong food with every bite they take.

Funds raised by FAI are invested in research that seeks to find a cure and improve clinical treatment for food allergy, including food-induced anaphylaxis and chronic diseases of the skin and gastrointestinal tract caused by food allergy. FAI has established a Medical Advisory Board to identify and recommend the most promising research in the United States. FAI also provides grants to entities that serve and support food allergic patients and their families at The Mount Sinai School of Medicine in New York City.

In addition, it is FAI's mission to raise public awareness about the seriousness of food allergies. Through effective educational programs and public information, FAI heightens awareness of food allergies and the danger of anaphylaxis among the media, health care workers, education and child care professionals, while also working with the nation's policy makers to create a safer environment and improve care for the food allergic population.

Research

Before there can be a cure for a particular food allergy, we must identify the structure and genetic code of the proteins responsible for the allergic reaction. FAI established the *Food Allergy Genomic Initiative* at The Mount Sinai School of Medicine to decipher the proteins that cause the more prevalent allergies. With this information, researchers supported by FAI hope to develop "safe shots" designed to significantly reduce and perhaps cure a food allergy over time without exposing the individual to the risk of anaphylaxis during treatment. In addition, FAI's Medical Advisory Board seeks out innovative research in a quest for a cure.



Clinical Activities

By fostering a multi-disciplinary program involving allergists, immunologists, pediatricians, internists, gastroenterologists and nutritionists, FAI seeks to improve the identification and treatment of those at risk of food allergies.

Educational Programs

As the number of individuals with food allergies dramatically increases, FAI promotes increased sensitivity and awareness of food allergies and anaphylaxis. By targeting the media, health care workers, and education and child care professionals with our message, we hope to accomplish this goal.

Advocacy

FAI works to develop and implement public policies that improve the quality of life for the food-allergic population. FAI plays an integral role in establishing national, state, and local guidelines and programs for anaphylaxis. Currently, food induced anaphylaxis is not mandated by the Centers for Disease Control as a reportable event. FAI is working towards having this policy revised.

Living with Food Allergies

Studies have shown that food allergy seriously affects the quality of life of sufferers and their families. Food allergies differ from other allergies because even a minuscule amount of the wrong food can be fatal. Allergies to cats, dogs, and rag-



weed, while uncomfortable, are not usually life-threatening as the reactions are limited to sneezing and watery eyes or asthma. But allergic reactions to food can cause potentially deadly symptoms such as throat closing and loss of circulation.

Eating food, a simple act that most do without thought, can cause death within minutes for a food-allergic individual. For many, food allergies also cause daily symptoms such as debilitating itchy skin rashes and stomach problems that cause pain and growth failure.

Children are often left with very restricted diets because they are allergic to many common foods. Compounding the daily challenges faced by these sufferers and their families is the fact that avoiding food is a tricky process.

Dangerous trace amounts of the offending food found in poorly labeled processed foods, cross-contaminated utensils, and carried on the hands of others, pose a constant threat to those battling food allergies. A commercial product – perhaps one consumed and trusted as safe for years – may undergo an ingredient switch not clearly stated on the label, or be subjected to cross-contamination from shared processing equipment, creating potential disaster.

Children and adults who suffer from food allergies must be forever vigilant. They often carry doses of epinephrine in case of accidental ingestion. At present, epinephrine is the primary emergency treatment available to reduce the symptoms of anaphylaxis, and it can only buy time in the race for proper medical attention.

Food allergy sufferers must be able to trust that foods are accurately labeled; that chefs and wait-staff understand the issues and treat inquiries with the seriousness they deserve; and schools, camps and friends cooperate in following procedures that save lives.

Accomplishments of FAI

FAI was established by concerned parents and grandparents with the goal of accelerating the search for a cure by working together.

Since 1998: FAI has supported the expansion of the clinical activities of The Elliot and Roslyn Jaffe Food Allergy Institute at The Mount Sinai School of Medicine so that more patients can be tested, treated, and educated about their diagnosis and care.

In 1999: FAI established the *Food Allergy Genomic Initiative* which supports, on an on-going basis, the development of innovative immunotherapy treatments for potentially fatal food allergies by studying the genetic makeup of food proteins that cause allergic reactions.

With the guidance of U.S. Senator Daniel P. Moynihan, the budget for the National Institutes for Health was increased and, with this extra funding, food allergy research will be expanded.

FAI was instrumental in securing passage of New York State legislation authorizing ambulance personnel to carry and administer epinephrine. Now, citizens can get this medication outside of the hospital in the early stages of an anaphylactic reaction—a key factor in saving lives.

In 2000: In collaboration with the Food Allergy Network, FAI sponsored a video to train Emergency Medical Technicians to recognize and treat anaphylaxis with epinephrine.

FAI founded an *International Council* to increase communication about food allergies among opinion leaders from Asia, Australia, Europe, and the United States.

FAI developed a pilot program to educate chefs and members of the hospitality industry about food allergies and cross-contamination so individuals with food allergies can dine without fear. The chefs, managers and staff of a number of prominent restaurants have received this training.

In 2001: FAI is continuing to educate the hospitality industry, medical personnel, schools, camps and government officials through numerous programs and initiatives. In addition, FAI has committed over \$2 million to research to find a cure.

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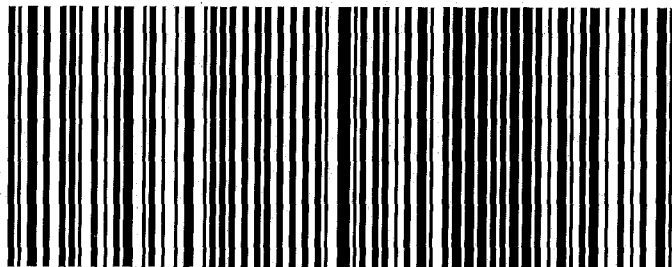
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