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October 29, 2001

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Attorney General of Pennsylvania

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

Re: Docket No. OOP-1322

Dear Sir or Madam:

We, the undersigned Attorneys General, are providing written comments regarding labeling of food products containing allergens, in response to the Federal Register notice of July 25, 2001 (Federal Register Volume 66, No. 143, pages 38591 to 38594). These comments are submitted in addition to oral testimony provided by Judith S. Schreiber, Ph.D., Senior Public Health Scientist, Office of the New York Attorney General, at a public hearing on August 13, 2001.

Attorneys General of nine states¹ submitted a petition in May 2000, asking the FDA to amend its regulations on food labeling and manufacturing practices to better protect consumers from exposure to potentially life threatening food allergens. We have attached a copy of the May 2000 Petition ("Petition") so it can be entered into the docket. We are grateful that the FDA is taking consumers' concerns seriously and has made strides to address these important health issues. We appreciate the FDA's efforts to seek public comment to aid the agency in determining further steps to that end.

In the Petition, the Attorneys General asked that the FDA:

¹ Connecticut, Maryland, Massachusetts, Michigan, New York, Ohio, Tennessee, Vermont, and Wyoming.

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1. Require food manufacturers to label products with actual or possible presence of allergenic substances in a food, by amending 21 CFR Section 101.17 (see pages 4-6 of Petition).
2. Require food manufacturers to provide a toll-free number to enable consumers to contact knowledgeable customer service representatives about the ingredients contained in the food, by amending 21 CFR Section 101.17 (see pages 6-7 of Petition).
3. Require food manufacturers to declare natural flavors derived from milk, eggs, fish, crustacea, mollusks, wheat, tree nuts, peanuts or soybeans, by adding subparagraph (8) to 21 CFR §101.22 (h) (see pages 7-8 of Petition).
4. Require food manufacturers to declare incidental additives derived from milk, eggs, fish, crustacea, mollusks, wheat, tree nuts, peanuts, or soybeans, by adding subparagraph (5) to 21 CFR 101.100(a) (see page 8 of Petition).
5. Require food manufacturers to adopt good manufacturing practices aimed at preventing cross-contamination with allergenic substances, by adding subpart H to 21 CFR Part 110 (see pages 9-11 of Petition).

We reiterate the need for the FDA to have mandatory requirements to ensure the safety of the food supply for all Americans. With regard to the specific questions posed in the Federal Register notice, we offer the following comments:

1. Regarding source labeling, we urge the FDA to require food manufacturers to include mandatory plain English terms for the eight most common food allergens. We believe plain English terms are fairly easily identified as those that most people recognize and understand.

We recommend the use of common terms such as “milk,” “eggs,” “fish,” “shellfish,” “wheat,” “treenuts,” “peanuts,” and “soybeans.” Technical terms such as “caseinate,” “albumin,” and “crustacea” should not be used.

Mandatory language, we believe, is the only way to assure that the label contains the necessary information upon which consumers can make an educated choice about the safety of the food for their family’s circumstances. (see pages 4-7 of Petition).

2. Regarding advisory labeling and good manufacturing practices, we urge the FDA to exercise its authority and adopt the recommendations in the Attorneys General petition. Advisory labels are the **consumers’ lifeline** to knowledge about potentially harmful allergenic food ingredients. (see pages 4-7 and pages 9-11 of Petition).
3. We agree with the FDA that the declaration of allergenic ingredient additives in spices and colors is necessary for consumer protection. The Petition of the Attorneys General recommends amending the regulations for flavorings derived from one of the eight most common allergenic substances to require the declaration of the presence of the allergen, such as peanut flavoring. The information on allergenic components of flavorings, spices and

colors must be required by FDA to be included on the ingredient list using common or usual names. (see pages 7-8 of Petition).

We urge the FDA to codify its policy to specifically state that incidental additives that are food allergens are not exempt from labeling and must be declared in the ingredient statement on the label.

4. As presented in the Petition, we further urge the FDA to require mandatory labeling to appear prominently and conspicuously on the information panel or principal display panel of the package label. (see pages 4-6 of Petition).

In addition to advisory labels, the Petition asks that the FDA require food manufacturers to include a toll-free number that consumers may call to talk to trained and knowledgeable customer service representatives concerning the ingredients contained in the food. (see pages 6-7 of Petition).

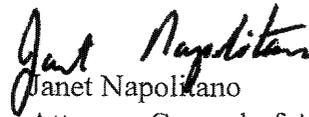
We urge the FDA to craft a mandatory, generally-applicable policy for all allergenic components of flavorings, spices and colors, and for incidental additives. Although the food industry has argued that their voluntary guidelines offer sufficient protection, it is clear from testimony of allergenic consumers and from the number of product recalls that these guidelines do not provide adequate protection from these life-threatening encounters with unlabeled allergens. We believe that mandatory measures are necessary and far superior to voluntary guidelines proposed by the food industry.

In closing, we thank the FDA for the opportunity to voice our concerns regarding this serious public health issue. If you have questions or comments, please contact Lynne Ross, NAAG's Executive Director, at (202) 326-6053.

Sincerely,



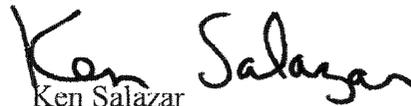
Bruce M. Botelho
Attorney General of Alaska



Janet Napolitano
Attorney General of Arizona



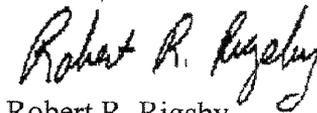
Bill Lockyer
Attorney General of California



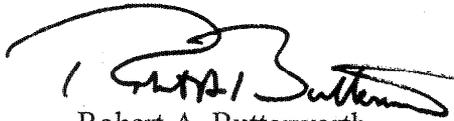
Ken Salazar
Attorney General of Colorado



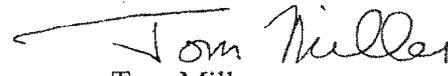
Richard Blumenthal
Attorney General of Connecticut



Robert R. Rigsby
Corporation Counsel of
District of Columbia



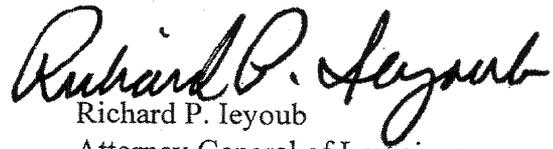
Robert A. Butterworth
Attorney General of Florida



Tom Miller
Attorney General of Iowa



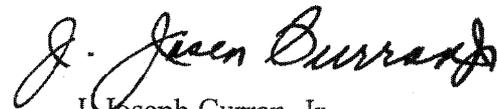
Carla J. Stovall
Attorney General of Kansas



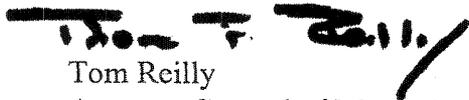
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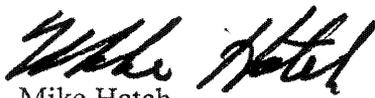
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Tom Reilly
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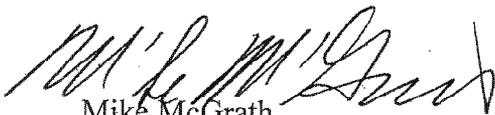
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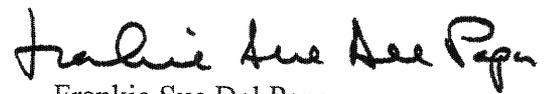
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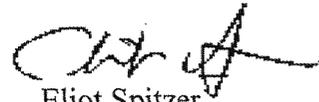


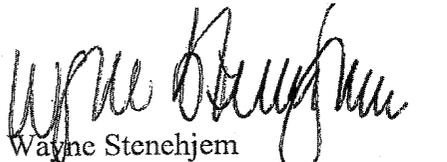
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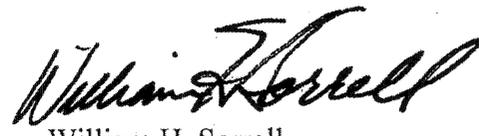

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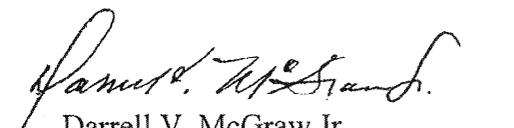

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CITIZEN PETITION

The Attorneys General of the states of New York, Maryland, Michigan, Wyoming, Ohio, Tennessee, Connecticut, Vermont and Massachusetts submit this petition to request action by the Food and Drug Administration ("FDA") regarding allergenic substances. Specifically, the undersigned request the Commissioner of Food and Drugs to amend the following parts and sections of Title 21 of the Code of Federal Regulations (C.F.R.) so as to provide adequate protection and notice to people with food allergies:

- § 101.17
- § 101.22 (h)
- § 101.100 (a)
- Part 110.

This petition is submitted pursuant to § 4 (d) of the Administrative Procedure Act, 5 U.S.C. § 553 (e) and 21 C.F.R. § 10.30 and pursuant to §§ 201(n), 402(a), 403(a) and 403(i) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § § 321 (n), 342 (a), 343 (a) and 343(i).

I. INTRODUCTION

Approximately 35-40 million people in the United States (15-20 percent of the population) report suffering from some type of allergy.¹ The cause of allergic reactions ranges from insect bites and stings to drugs, environmental factors and food. Roughly five million

¹American College of Allergy, Asthma, and Immunology, *Children's Allergies* (visited Aug. 12, 1999) <<http://allergy.mcg.edu/Advice/chldrn.html>>.

Americans² or two percent of adults and two to eight percent of children, are allergic to various types of foods.³ Of these, three million Americans suffer from peanut and tree nut allergies.⁴ Allergies to food are particularly dangerous for three reasons. First, unlike certain insect and environmental allergies, which can be medically managed through the use of immunotherapy and medications, there is currently no medical treatment available to prevent allergic reactions to food. The only method to manage a food allergy, therefore, is to strictly avoid the offending food.⁵

As will be discussed in the Statement of Factual Grounds, however, despite a person's best efforts, it can be very difficult to avoid allergenic foods. Each year hundreds and possibly thousands of Americans suffer severe or fatal reactions to food, even after taking precautions to avoid these occurrences.⁶ Often the reactions are the result of imprecise labeling of the ingredients contained in the products that these individuals have consumed.

² Constance Hays, *Awareness Grows of Allergic Reactions to Nuts, Dangerous to Millions*, N.Y. TIMES, Feb. 22, 1998 § 1 page 12 column 5.

³ *Food Allergies: Rare but Risky*, FDA CONSUMER MAGAZINE, Dec. 1993, at 94.

⁴ Dan Vergano, *Vague labels gnaw away at choices for peanut-allergic*, USA TODAY, Dec. 6, 1999, § D page 10 column 1 and Sicherer, Scott M.D., Anne Munoz-Furlong, B.A., A. Wesley Burks M.D., Hugh A. Sampson M.D., *The Prevalence of Peanut and Tree Nut Allergies in the US determined by a random digit dial telephone survey*, 103 JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY 559 (1999).

⁵ Hugh A. Sampson, M.D., *Fatal food induced anaphylaxis*, 53 ALLERGY 125, 129-130 (1998).

⁶ *Id.* at 125 and S. Allen Bock, *The incidence of severe adverse reactions to food in Colorado*, 90 JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY 683 (1992).

The second factor that distinguishes food allergies from other types of allergies is the severity of the reaction that may follow exposure to allergenic foods. Individuals with food allergies are at higher risk for suffering a severe allergic reaction known as anaphylaxis.

Anaphylaxis is a swift and violent reaction that simultaneously affects various organ systems, including the skin, upper and lower respiratory system, cardiovascular system, eyes, uterus and bladder. If left untreated, anaphylaxis can cause death in a matter of minutes.⁷

A third factor which distinguishes food allergies is the variety of situations in which they may occur. People very careful about the food that they prepare at home remain vulnerable at restaurants, schools and other public eating places. New allergies can appear and cause unexpected reactions. To date, however, no national incidence study of food-induced anaphylaxis has been conducted. At present, therefore, we do not know precisely the circumstances in which food related anaphylaxis occurs in the United States, *e.g.* the number of allergic reactions attributable to misleading food labels versus the number of first-time reactions.

While anaphylaxis is a severe and dramatic reaction to many allergies, it is a daily reality for the millions of Americans who have food allergies. A small mistake or hidden ingredient can lead to severe reactions. It is thus essential for the health and safety of these individuals that food labels provide complete and accurate ingredient information. Under current federal regulations, however, manufacturers are not required to specifically identify allergenic ingredients on food labels when they are included in the product as “natural flavors” or as “incidental” additives.

⁷ DEY L.P., ANAPHYLAXIS - THE EXTREME ALLERGIC REACTION (1998) and Sampson, *supra* note 5, at 127.

Moreover, the current good manufacturing practices promulgated by the FDA for the food industry do not include measures to avoid the contamination of foods with allergenic substances. The purpose of this petition is to address these deficiencies in the current regulations and provide more accurate, complete and potentially lifesaving ingredient information to allergy sufferers.

II. ACTION REQUESTED

1. 21 C.F.R. §101.17 requires food manufacturers to include various warnings and notice statements in food labels. The undersigned request the Commissioner to address allergenic food substances by adding paragraph (h) to Section 101.17, requiring manufacturers to warn consumers of the actual or possible presence of allergenic substances in a food product, as follows:

(h) Foods containing allergenic substances.

(1) Foods containing milk, eggs, fish, crustacea, mollusks, tree nuts (*e.g.*, walnut, almond, cashew), wheat, peanuts or soy beans (hereafter referred to as “allergenic substances”) shall bear a label statement informing consumers of the presence of such substances (*e.g.*, **ALLERGEN INFORMATION:**

This product contains egg and soy).

(2) Foods that may contain allergenic substances

due to migration of such substances from equipment or packaging or otherwise shall bear a label statement informing consumers of the possible presence of such substances (*e.g.*, **ALLERGEN INFORMATION:**
May contain peanuts.)

(3) The statements required by paragraphs (h) (1) and (2) of this section shall appear prominently and conspicuously on the information panel or principal display panel of the package label and any other labeling to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The statements shall be preceded by the words “**ALLERGEN INFORMATION**” in capital letters.

(4) In addition to the labeling statements required by paragraphs (h) (1), (2) and (3) of this section, foods which contain or may contain allergenic substances shall bear the following insignia:



Such insignia shall appear prominently and conspicuously on the front right hand upper corner of the product package.

2. As discussed in more detail in the Statement of Factual Grounds, a food-allergic consumer can often encounter difficulties in obtaining necessary and accurate information concerning product ingredients from food manufacturers. Accordingly, the undersigned request the Commissioner to add paragraph (i) to 21 C.F.R. §101.17, as follows:

(i) Consumer Information. (1) The label of a food that is subject to the requirements of Section 403 (i) (2) of the Act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients) shall include a toll-free number that consumers may call to talk to trained and knowledgeable customer service representatives concerning the ingredients contained in the food.

(2) The toll-free telephone

number shall appear prominently and conspicuously on the package label.

(3) A food manufacturer may meet the requirements of paragraph (i) (1) and (2) of this section through the use of its own personnel or by participating in a centralized information source established by a manufacturers' association, trade group or other such third party that provides equivalent information as in (i)(1) above.

3. 21 C.F.R. §101.22 permits manufacturers to declare natural flavor derived from plant and animal sources as "natural flavor." As noted in the Statement of Factual Grounds, below, however, when a flavoring is derived from milk, eggs, fish, crustacea, mollusks, wheat, tree nuts, peanuts or soy beans, the use of the term "natural flavor" can lead to the unintended ingestion of these substances by food-allergic consumers. Accordingly, the undersigned request the Commissioner to add subparagraph (8) to 21 C.F.R. §101.22 (h), as follows:

(8) Any flavoring derived from milk, eggs, fish, crustacea, mollusks, wheat, tree nuts, peanuts or soybeans shall be declared by its usual or common name (*e.g.*, peanut flavoring).

4. 21 C.F.R. §101.100 (a)(3) exempts incidental additives, such as processing aids, “that are present in a food at insignificant levels” from compliance with the requirements of Section 403 (i) of the Federal Food, Drug, and Cosmetic Act. As discussed more thoroughly in the Statement of Factual Grounds, below, however, what a manufacturer may deem to be present at an insignificant amount may not be insignificant to a food-allergic consumer, because even a small amount of an allergenic substance can cause a severe reaction. Accordingly, the undersigned request the Commissioner to amend §101.100 (a) to add subparagraph (5) as follows:

(5) For the purposes of paragraph (a)(3) of this section, no incidental additives derived from milk, eggs, fish, crustacea, mollusks, wheat, tree nuts, peanuts or soy beans shall be considered to be present in a food at insignificant levels and such incidental food additives must be declared as required by section 101.17(h) of this chapter.

5. 21 C.F.R. Part 110 sets forth “Good Manufacturing Practices” aimed at preventing the adulteration of food with contaminants such as microorganisms or hazardous chemicals. As

described in the Statement of Factual Grounds, below, however, foods that contain even trace amounts of allergenic substances can be as deadly to food-allergic consumers as adulterated food is to ordinary consumers. Allergenic ingredients are often inadvertently introduced into a food through “cross-contamination,” *i.e.* the migration of the substances from adjacent production lines and/or shared equipment or facilities. Accordingly, the undersigned request the Commissioner to add Subpart H to Part 110, requiring manufacturers to adopt good manufacturing practices aimed at preventing cross-contamination with allergenic substances, as follows:

SUBPART H - ALLERGENIC SUBSTANCES

§ 110.20 Measures to prevent the migration of allergenic substances from equipment, packaging or otherwise.

(a) The plant management shall take all reasonable measures and precautions to ensure that substances derived from milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, peanuts or soy beans (hereafter “allergenic substances”) do not

migrate to food from equipment, packaging or otherwise. These measures shall include, but are not limited to the following:

1) Dedication of facilities, personnel, equipment and utensils to foods that do not contain allergenic substances (*e.g.*, dedication of a plant or production line to nut free products).

2) Physical separation of personnel, facilities, equipment and utensils used to produce foods containing allergenic substances from personnel, facilities, equipment and utensils used to produce foods that do not contain allergenic substances.

3) Sanitation of equipment and utensils used to produce foods containing allergenic substances before such equipment and utensils are used to produce foods that do not contain allergenic substances.

4) Scheduling of production to ensure that foods not

containing allergenic substances are processed prior to production of foods that contain allergenic substances (e.g., producing peanut flavored ice cream after non-peanut flavored ice cream is processed and just before processing equipment is scheduled for sanitation).

5) Exclusion of allergenic substances from reworked food products (e.g., exclusion of peanut flavored ice cream from reworked chocolate ice cream).

6) Periodic utilization of assays to determine whether allergenic substances are migrating from equipment, packaging or otherwise to finished products.

b) In instances where despite reasonable measures and precautions, migration of allergenic substances from equipment, packaging or otherwise has occurred or is likely to

have occurred, foods shall be labeled in accordance with the requirements of Section 101.17 (h) of this chapter. However, in no event shall such labeling be used in lieu of adherence to the requirements set forth in paragraph (a) of this section.

III. STATEMENT OF FACTUAL GROUNDS

A food allergy is defined as when the immune system recognizes a “reaction-provoking substance, or allergen, as foreign” and produces antibodies “to halt the invasion.”⁸ The foods that most commonly cause allergic reactions are: milk, eggs, fish, crustacea, mollusks, wheat, tree nuts, peanuts and soy beans⁹ (hereafter “allergenic substances”). In fact, 90% of all food allergies are related to these nine substances.¹⁰ It is possible for some individuals to outgrow food allergies, particularly: milk, soy, eggs, wheat and others. However, nut allergy, especially peanut, is usually lifelong. The theory behind outgrowing food allergy has to do with maturation of the gastro-intestinal tract with age, and its ability to prevent absorption and presentation of

⁸ *Food Allergies: Rare but Risky*, *supra* note 3 at 94.

⁹ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 104, 22987 (1992).

¹⁰ Food Allergy Network., *Food Allergy Facts and Fiction* (visited Aug. 18, 1999) <http://www.foodallergy.org/facts_fiction.html>.

certain allergenic food components to the immune system. Peanut allergens seem to avoid that “gate keeping” mechanism of the gastro-intestinal tract.¹¹ This means that individuals allergic to these substances must undertake specific safeguards to prevent adverse reactions to these foods for their entire life.

As previously mentioned, an allergic reaction to food can be so severe that the individual experiences anaphylaxis. In fact, food-induced allergic reactions are believed to be the most common cause of anaphylaxis.¹² Anaphylaxis is a rapid, severe response that occurs when a person is exposed to an allergen to which he or she has been previously sensitized. The reaction is brought on when the allergen enters the bloodstream, causing the release of chemicals throughout the body that try to protect it from the foreign substance. Symptoms that signal the onset of anaphylaxis include:

- Itching of the skin and raised rash (hives);
- Flushing, swelling of the lips, throat, tongue, hands and feet;
- Wheezing, shortness of breath, coughing, hoarseness;
- Headache;
- Nausea, vomiting, abdominal cramps;
- Sense of impending doom, loss of consciousness;¹³

¹¹ Letter from Jocelyn Celestin, M.D., Chief, Division of Allergy and Immunology and Assistant Professor of Medicine and Pediatrics, Albany Medical College (October 27, 1999).

¹² Sampson, *supra* note 5, at 125.

¹³ DEY L.P., *supra* note 7.

- Arrhythmia¹⁴ (abnormal heartbeat¹⁵);
- A precipitous drop in blood pressure.¹⁶

What makes anaphylaxis a terrifying condition is the speed at which an individual's life becomes endangered. Symptoms are usually seen within five to fifteen minutes after ingestion. Additionally, approximately one-third of allergic patients experience biphasic reactions. In this situation, individuals develop classical symptoms and appear to recover only later to see a recurrence with catastrophic, and even fatal, symptoms.¹⁷ S. Allen Bock, M.D., an allergy researcher, states that a "minimum of 950 severe reactions to food may occur each year."¹⁸ Hugh A. Sampson, M.D., another expert in food allergies, estimates as many as 2,500 food-induced anaphylactic reactions may occur in the United States each year with 125 fatalities resulting.¹⁹ During the early 1990s, the Public Health Service's International Classification of Diseases began coding death and injury due to anaphylactic shock due to adverse food reactions including specified and unspecified foods, peanuts, crustaceans, fruits and vegetables, tree nuts and seeds,

¹⁴ Sampson, *supra* note 5 at 127.

¹⁵ Douglas M. Anderson, M.A., et al., DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 121 (28th ed. 1994).

¹⁶ Sampson, *supra* note 5, at 127.

¹⁷ *Id.* at 126.

¹⁸ Bock, *supra* note 6, at 683.

¹⁹ Sampson, *supra* note 5, at 125.

fish, food additives, milk products and eggs.²⁰ The adoption of such detailed codes will result in development of more accurate data on the prevalence of food-related anaphylactic outcomes. While a careful review of articles discussing food allergies will reveal some differences in estimates of the numbers of people affected by food allergies and the number and type of severe outcomes, the numbers are still significant enough to warrant concern and implementation of reforms to reduce risks.

Antihistamines, which are often sufficient to treat environmental allergies, are not effective in treating allergic reactions to food. This stems from the fact that when an allergic reaction to food occurs, histamine is only one of the many chemicals involved. Several other substances are released that cause the clinical manifestations,²¹ e.g. bradykinin (a nonapeptide produced by activation of the kinin system during inflammatory conditions²²), leukotrienes (compounds which cause bronchial constriction²³) and prostaglandins (substances produced by mast cells which effect vasodilation and contraction of nonvascular smooth muscle²⁴).

²⁰ U.S. Department of Health and Human Services, Public Health Service. THE INTERNATIONAL CLASSIFICATION OF DISEASES, Vol. 1, Addendum, CD-9-CM, § 995.6 page 867 (4th ed. 1993) - [the 1991 issue - 9th revision - did not include section 995.6, see page 867].

²¹ Celestin, *supra* note 11, and Micheal W. Yocum M.D. and David A. Khan M.D., *Assessment of patients who have experienced anaphylaxis: a 3-year survey*, 69 MAYO CLINIC PROC. 16-23, (1994)

²² Anderson, *supra* note 15, at 223-224.

²³ *Id.* at 922

²⁴ *Id.* at 1365-1366.

Furthermore, a variety of cells are activated, producing multiple substances that positively feed back the reaction. Antihistamines, which are drugs that prevent the cellular effects of histamine, are thus of limited value when dealing with food allergies.²⁵ The preferred method of treating a patient who is experiencing food-induced anaphylaxis is the administration of epinephrine (adrenaline).²⁶ Epinephrine works directly on the cardiovascular and respiratory systems to counter the effects of anaphylaxis by rapidly constricting the blood vessels, relaxing muscles in the lungs to improve breathing, reversing swelling and stimulating the heartbeat.²⁷ Epinephrine must be injected within minutes of the reaction to be effective and is usually followed by hospitalization and administration of steroids and other powerful drugs. Without such intervention, death may ensue.²⁸

Allergens are often found in foods even when the labels give no indication that they are present. Consumption of those foods can be harmful and possibly fatal. An incident experienced by Steven F. Kemp, M.D. is typical. Dr. Kemp is a physician specializing in allergies and immunology. He also happens to have a medical history that includes allergic asthma and anaphylaxis induced by peanuts, almonds and pecans. In 1996 at the age of 34, Dr. Kemp ingested approximately 20 commercially-made gingersnap cookies. The package label did not list peanuts among the ingredients. Within five minutes of ingestion, he suffered palatal itching,

²⁵ Celestin, *supra* note 11.

²⁶ Sampson, *supra* note 5, at 129.

²⁷ DEY L.P., *supra* note 7.

²⁸ Sampson, *supra* note 5, at 128-129.

dysphagia (swelling of the esophagus²⁹), abdominal cramps, tachycardia, bronchospasm, general erythema (redness of the skin³⁰), peripheral cyanosis, lightheadedness, rhinitis (swelling of the nasal mucous membrane³¹) and conjunctivitis. Prescription drugs, epinephrine and loratadine, were self-administered and the prompt relief of symptoms ensued. At the hospital's emergency facility 30 minutes later, however, recurrent bronchospasm, intense pruritus (itching³²) of the palms and generalized urticaria occurred and necessitated the administration of additional epinephrine, antihistamine, and intravenous steroids with the resolution of symptoms. Dr. Kemp suspected peanut cross-contamination since the last similar experience of such severe symptoms occurred 28 years earlier after an accidental ingestion of a peanut butter cookie. The cookies were tested and found to contain at least 179.2 micrograms per milliliter of peanut antigen. The manufacturer was unable to find the source of this peanut contamination and insisted that it fully complied with existing federal good manufacturing practices.³³

As the Dr. Kemp case illustrates, food-allergic consumers often find it difficult to avoid allergenic ingredients even when they make an effort to do so. There are several reasons for these types of occurrences:

²⁹ Anderson, *supra* note 15, at 517.

³⁰ *Id.* at 576-577.

³¹ *Id.* at 1459.

³² *Id.* at 1374.

³³ Stephen F. Kemp, M.D. and Richard F. Lockey, M.D. *Peanut Anaphylaxis From Food Cross-Contamination*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, JAMA Letters, June 5, 1996.

Hidden Ingredients

Allergens can be found where one least expects them to be. For example, peanuts and tree nuts, to which three million Americans are allergic,³⁴ are often included as a “hidden” ingredient in such varied foods as candy, biscuits, pastry, chili and egg rolls.³⁵ A consumer is less likely to review an ingredient list if the food he or she is about to consume does not normally contain an allergenic substance such as peanuts. For this reason, affirmative warning labels are urgently needed to alert consumers as to the presence of allergenic ingredients.

Natural Flavorings

When used as flavorings, allergenic substances are often not declared by name on food labels.³⁶ According to Fred R. Shank, Ph.D., the former Director of the Center for Food Safety and Applied Nutrition, this practice has led to instances in which consumers have unintentionally ingested allergenic substances and have suffered adverse reactions as a consequence.³⁷ If food

³⁴ Vergano, *supra* note 4 and Sicherer M.D. *et al.*, *supra* note 4, at 562.

³⁵ Kemp, *supra* note 33.

³⁶ Fred. R. Shank, Ph.D., *Label Declaration of Allergenic Substances in Foods*, FDA Notice to Manufacturers (June 10, 1996).

³⁷ *Id.* Freedom of Information Act (F.O.I.A.) requests have been made to the FDA December 30, 1999 and June 29, 1999 in order to obtain the bases for the Notice to Manufacturers signed by Dr. Shank. The New York Attorney General F.O.I.A. requests seek FDA data, research and other information that describe the nature, prevalence and severity of food allergies so as to supply additional justification for the reforms sought in this petition. The documents that FDA has supplied to date addressed complaints that FDA has received concerning intolerance to various food additives but did not address the bases to Dr. Shank’s Notice or reports of adverse reactions to any of the common naturally occurring food allergens.

manufacturers were required to declare natural flavors which are derived from allergenic substances by their common or usual name, these occurrences could be avoided.

Incidental Additives

Food manufacturers are currently permitted under federal regulations to omit “incidental additives,” such as processing aids, from food labels when such additives are present at “insignificant levels.”³⁸ However, as the FDA’s own expert has opined, “because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level.”³⁹ For example, studies have shown that exposure to as little as one-fifth to one-five-thousandth of a teaspoon of the allergenic substance can cause a reaction which could potentially lead to death.⁴⁰ According to Dr. Shank, the failure to declare incidental additives which are derived from allergenic substances has resulted in many instances of adverse reactions.⁴¹ Such reactions could be avoided if manufacturers were required to declare all additives derived from allergenic ingredients regardless of the level at which they are present in the finished food product.

Cross-Contamination

³⁸ 21 C.F.R. 101.100 (a)(3)

³⁹ Shank, *supra* note 36.

⁴⁰ *Food Allergies: Rare but Risky*, *supra* note 3.

⁴¹ Shank, *supra* note 36.

As the Dr. Kemp case illustrates, allergenic substances can make their way into supposedly non-allergenic products even when manufacturers fully comply with the good manufacturing practices that are currently mandated under federal regulations. These regulations, however, do not address the problem of “cross-contamination.” Cross-contamination occurs when allergenic substances migrate from equipment, utensils or packaging material into foods which are intended to be allergenic free. For example, in a bakery that is manufacturing two food products on one production line, one product with peanuts and the other one without, traces of peanuts, or peanut products, may end up in the product that does not contain peanuts.⁴² If manufacturers were required to take steps to avoid cross-contamination, food-allergic consumers would be less likely to accidentally ingest allergenic foods.

Some manufacturers recognize the problem of cross-contamination and label their products to alert consumers as to the actual or possible presence of allergens. Because this practice is not mandated, however, consumers remain at risk for accidental ingestion of food allergens. For example, Brach and Brock Confections, Inc. produces a number of candy products, including candy corn and jelly beans. The labels for these particular products neither list peanuts as an ingredient nor warn consumers of the possible presence of peanuts. When C.M.T, the mother of a peanut allergic child, recently contacted the company, however, she was advised not to serve Brach’s candy corn or jelly beans to her daughter, since these products were packaged on the same equipment used to package peanut-flavored candies and potentially

⁴² *Id.*

contained trace amounts of peanuts.⁴³ Absent this telephone call, C.M.T. would have never known of the danger that these products posed to her daughter. As this case demonstrates, consumers cannot currently rely on food labels to alert them of instances where cross-contamination has occurred or may have occurred.

Inability to Obtain Additional Product Information

As the C.M.T case illustrates, a food-allergic consumer often requires information in addition to that set forth in a food label in order to determine if a product is safe to eat. Although many food manufacturers invite consumers to call or write to them for further information, this practice is by no means universal. In fact, according to an informal survey recently conducted by members of the New York Nut Allergy Awareness Group, Inc., numerous food manufacturers do not include a toll-free telephone number on their product labels.⁴⁴ Consumers are thus left with the task of ferreting out their appropriate address or telephone number, often expending considerable time and expense in the process. When a consumer manages to track down the manufacturer of a product, there is no guarantee that knowledgeable staff will be available or possess sufficient and accurate information to answer his or her questions. Such was the case when M.A.C., a mother of two food-allergic children, attempted to obtain additional product information concerning Farina Mills® Enriched Farina Creamy Hot Wheat Cereal. Although M.A.C. made 19 telephone calls, many long-distance, she was not even able to determine who

⁴³ Letter from parent of food allergic child, Catherine M. Tretheway, to Peter Skinner P.E., scientist at the New York State Attorney General's Office (November 8, 1999).

⁴⁴ New York Nut Allergy Awareness Group, Inc., *Survey of Local Grocery Store Shelf Contents*, October 1, 1999 attached as Exhibit A.

manufactured the product, much less how it was produced.⁴⁵ It should not be this difficult to obtain necessary product information from manufacturers. The current FDA regulations, however, do not address this problem.

The above-cited examples of the obstacles faced by food-allergic consumers in selecting safe food products are by no means unique. Attached hereto as Exhibit B are letters received by the New York State Attorney General's Office during the course of preparing this petition. These letters and the other exhibits attached hereto clearly show the urgency of and various approaches to structuring improved labeling and manufacturing protocols. In order to address these needs, the undersigned propose the following amendments to Title 21 of the Code of Federal Regulations:

- Section 101.22(h): prohibit the use of the term "natural flavoring" to describe flavorings derived from allergenic substances;
- Section 101.100(a)(3): exclude allergenic substances from the definition of incidental additives;
- Part 110: add a new Subpart H to require manufacturers to take all reasonable measures and precautions to avoid the migration of allergenic substances from equipment and utensils to non-allergenic foods; and
- Section 101.17: require manufacturers to warn consumers of the actual or possible presence of allergenic ingredients in the food product and provide consumers with a toll-free number and/or central depository to obtain product information.

These proposed amendments to the Title 21 regulations will admittedly have an economic

⁴⁵ *Letter* from parent of food allergic children, Mary Ann Colegrove, to Peter Skinner P.E., scientist with the New York State Attorney General's Office (November 11, 1999).

impact on some food manufacturers.⁴⁶ Greater scrutiny may have to be paid to ingredients used in products even when present at “negligible” levels. Production processes may have to be modified to avoid the migration of allergenic substances. Staff may have to be trained to maintain consumer information lines and keep data up to date. Those manufacturers that do not already possess toll-free telephone lines will incur the additional cost of operating these telephone lines. The proposed food labeling regulation changes, however, should generate insignificant new expense. Moreover, the benefits that the proposed changes will provide to consumers far out-weigh any implementation costs. Food-allergic individuals will have greater freedom in choosing safe foods and do so more reliably, fewer hospitalizations will be necessary and fewer incidences of suffering and death will occur from inadvertent ingestion of allergenic ingredients. A reduction in ingredient information ambiguity will allow individuals to locate and select safe foods and will provide greater safety and assurance for over five million Americans and their families.

IV. STATEMENT OF LEGAL GROUNDS

The FDA has both the legal authority and ample precedent for responding to the needs of the five million food-allergic consumers living in the United States by requiring food manufacturers to declare allergenic substances on food labels and taking the other steps requested in this petition.

⁴⁶ Vergano, *supra* note 4.

The Federal Food, Drug and Cosmetic Act (FDCA) prohibits the introduction into interstate commerce of any food that is misbranded. 21 U.S.C. § 331 (a). In the case of any food that is fabricated from two or more ingredients, the food is deemed to be misbranded unless its label bears the common or usual name of each such ingredient. 21 U.S.C. § 343 (i). Several exemptions to this definition have been carved out by statute and regulation, two of which are significant to food-allergic consumers. The first pertains to spices, flavorings and colors, which may be collectively designated on food labels as spices, flavorings and colorings without naming each. 21 U.S.C. § 343 (i); 21 C.F.R. 101.22 (h) (1). The second exemption pertains to incidental additives, which need not be declared if present in a food at “insignificant levels.” 21 C.F.R. § 101.100 (a) (3).

As discussed in the Statement of Factual Grounds, above, however, the use of the term “natural flavor” to describe flavorings derived from allergenic substances has led to the unintended consumption of such substances by food-allergic consumers. Likewise, the omission of incidental additives derived from allergenic substances from food labels has caused many instances of accidental ingestion by individuals with food allergies. For food-allergic consumers, therefore, these exemptions represent a serious health risk.

The definition of a misbranded food also includes any food with labeling that is false or misleading in any particular. 21 U.S.C. 343 (a). The statute defines “misleading” broadly: labeling can be found misleading not only for its representations, but also for its failure to reveal material facts about the consequences that may result from a product’s use under prescribed, customary or usual conditions. See 21 U.S.C. § 321 (n). Food labels that do not declare

allergenic ingredients because they consist of either natural flavorings or incidental additives are misleading to food-allergic individuals since they do not provide sufficient information to permit such consumers to select foods that are safe for them to eat. Thus, the presence of these allergenic substances is a material fact that must be disclosed on food labels; without such disclosure, the foods are misbranded. See 21 U.S.C. §§ 321 (n), 343 (a) (1).

The FDA has the authority to promulgate regulations for the efficient enforcement of the FDCA. 21 U.S.C. § 371 (a); 21 C.F.R. § 5.10 (a) (1). Thus, part of the Agency's mandate is to issue regulations to prevent the misbranding of foods. See 21 U.S.C. § 331 (a).

The FDA has previously seen fit to exercise this authority by promulgating regulations which have eliminated the natural flavoring and incidental additives exemptions as they pertain to certain food substances. Agency regulations require, for example,

- that any monosodium glutamate used as an ingredient in food be declared by its common or usual name "monosodium glutamate." 21 C.F.R. § 101.22 (h) (5);
- that the source of protein in hydrolysate used for its effect on flavor be identified. 21 C.F.R. § 101.22 (h) (7); and
- that any sulfiting agent added to food be declared if present in a "detectable" amount (*i.e.* 10 parts per million). 21 C.F.R. § 101.100 (a) (4).

The need for the FDA to follow these precedents and eliminate the natural flavoring and incidental additive exemptions as they pertain to allergenic ingredients is overwhelmingly apparent in view of the increasing number of cases of accidental ingestion of food allergens and the sometimes dire consequences which follow.

In response to public safety concerns, the FDA has also promulgated affirmative labeling

requirements informing consumers of the proper use and possible dangers of the following products:

- Self-pressurized containers;
- Self-pressurized containers with halocarbon or hydrocarbon propellants;
- Food containing or manufactured with chlorofluorocarbons;
- Protein products;
- Dietary supplements containing iron or iron salts;
- Foods containing psyllium husk; and
- Unpasteurized juice. 21 C.F.R. § 101.17.

Given the great number of Americans who suffer from food allergies and who could potentially incur illness or death from ambiguous or insufficient food labels, it is incumbent upon the FDA to require similar warning labels on foods containing allergenic ingredients.

In addition to prohibiting the sale of any food that is misbranded, the FDCA prohibits the introduction into interstate commerce of any food that is adulterated. The definition of adulterated food includes foods that have been prepared, packed or held in insanitary conditions whereby it may have been rendered injurious to health. 21 U.S.C. § 342 (a) (4); 21 C.F.R. § 110.5 (a). As discussed in the Statement of Factual Grounds, above, allergenic ingredients can be inadvertently introduced into a food through “cross-contamination,” *i.e.*, the migration of such substances from equipment and utensils used to produce allergenic food. The ingestion of foods that have been contaminated in this manner has proven to be injurious to the health of many food-allergic consumers.

The FDA, under its authority to prevent adulteration, has in the past promulgated good

manufacturing practices designed to prevent the contamination of food with microorganisms, filth or other harmful substances. 21 C.F.R. Part 110. In like manner, the FDA should exercise its authority to prevent further illnesses or deaths of food-allergic consumers by requiring manufacturers to adopt good manufacturing practices aimed at preventing cross-contamination with allergenic substances. This action would advance the goal of the FDCA, which is to ensure the safety of the food supply in the United States.

Thus, the FDA will be acting within its mandate and with the support of precedent, as well as in the public interest, by granting this petition in its entirety.

V. CONCLUSIONS AND RECOMMENDATIONS

Certain food substances have the ability to pose serious health risks, with potentially fatal results, to numerous Americans. While those individuals attempt to avoid contact with all of those substances to which they experience adverse effects, they have often fallen prey to ambiguous or insufficient ingredient labeling. In order to ensure the safety and welfare of the five million United States citizens possessing food-related allergies, ingredient warnings, better labeling and reforms in the manufacturing process are warranted as a general business and manufacturing practice.

VI. ENVIRONMENTAL IMPACT

Petitioners believe the action requested in this petition has no significant environmental

impact.

VII. ECONOMIC IMPACT

Petitioners believe that the action requested in this petition has no significant negative economic impact. A more detailed statement of any positive and negative economic impacts shall be submitted under separate cover if requested by the Commissioner.

CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully submitted,
by the Attorneys General of

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