cc: HFA-305
Dockets-Allergens
OOP-1322

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 31, 2001

Ms. Deborah J. Alexander
3801 Connecticut Avenue, NW
#304
Washington, D.C. 20008

Dear Ms. Alexander:

This is in response to your letter to Secretary Thompson concerning ingredient labeling of foods. The Department has forwarded your letter to the Food and Drug Administration (FDA) for response.

We understand your concern about labeling foods containing allergens and recognize the kinds of problems you face in trying to exclude foods to which you are sensitive.

FDA's regulations require that foods made up from two or more ingredients bear a statement of ingredients on the label. The ingredients must be listed in descending order of frequency by weight and by their common or usual names [Title 21 Code of Federal Regulations (21 CFR), part 101.4 (enclosed)]. However, the Food, Drug, and Cosmetic Act allows spices, flavorings, and colorings to be declared collectively without naming each one. We recognize that occasionally these ingredients contain subcomponents, which are allergens. Additionally, FDA regulations exempt from ingredient declaration incidental additives such as processing aids that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food. Because allergenic substances may cause adverse reactions after ingestion of small amounts of the substance, the agency does not believe that an allergen can be present at an insignificant level, thus, they should always be listed in the ingredient statement.

The FDA published a Notice to Manufacturers on June 10, 1996, to address this issue with industry (enclosed). In that letter we suggested that manufacturers review their product formulations and asked that they declare in the ingredient list any processing aids that contain known allergens. In the 1996 Notice to Manufacturers we also suggested that manufacturers voluntarily declare an allergenic ingredient of a coloring, flavoring, or spice by naming the allergenic ingredient in the ingredient list.

Regarding your suggestion that restaurants list peanut product items on the menu, we believe that it may be feasible for certain types of restaurants (e.g., chain or fast food restaurants with standardized food preparation and ingredient specifications) to provide ingredient information.

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However, at this time the agency does not have enough information about the industry to determine the appropriateness and manner of requiring ingredient labeling by restaurants. While we do not have requirements for ingredient labeling of restaurant foods, FDA encourages such declarations on a voluntary basis. We believe that a brochure could be helpful to consumers in providing information on ingredients used in prepared foods when it is impractical for a restaurant to provide ingredient information for all menu items. Thus, the agency encourages restaurants to provide such information when practical. As we develop our policy on the use and labeling of allergens, we will consider the appropriateness of requiring labeling of allergenic substances present in restaurant foods.

You may be interested to know that one of FDA's priorities for the year 2001 is to examine the issue of food allergen labeling further. FDA recently published a Compliance Policy Guide on allergens after a review of FDA food recalls revealed that there has been an increase in findings of undeclared allergens in food during the last decade. This document provides the Agency's compliance staff, field investigators, and the regulated industry with guidance on the Agency's policy on allergens (enclosed).

In addition, FDA held a public meeting on August 13 in Washington, D.C., to discuss labeling foods containing allergens and the unintended addition of allergens to foods because of processing practices. The agency is accepting comments on the topics addressed at the public meeting until October 29, 2001, and will then consider whether further rulemaking is necessary.

We have also received a citizen petition (docket number 00P-1322) raising concerns similar to those raised in your letter. We will forward your letter to the Dockets Management Branch to be included with other letters responding to the petition. Please be assured that we will consider all comments before making a final decision on this issue.

In addition, you may wish to contact the National Institute of Health (NIH) via the Internet, for information on studies conducted at the National Institute of Allergy and Infectious Diseases (NIAID). The address is http://www.niaid.nih.gov/default.htm. I have enclosed a copy of the homepage for you.

I hope you find this information useful.

Sincerely,

Kristy Moran

Kristy Moran
Policy Analyst
FDA Executive Secretariat

Enclosures

cc: Dockets Management Branch

[Code of Federal Regulations]
[Title 21, Volume 2, Parts 100 to 169]
[Revised as of April 1, 1999]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR101.4]

[Page 15-19]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--CONTINUED

PART 101--FOOD LABELING--Table of Contents

Subpart A--General Provisions

Sec. 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by Sec. 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of Sec. 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with Sec. 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., ``Contains __ percent or less of _____'' or ``Less than __ percent of _____.'' The blank percentage within the quantifying statement shall be filled in with a threshold level of 2 percent, or, if desired, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying phrase applies may be present in an amount greater than the stated threshold.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of Sec. 101.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.

(ii) By incorporating into the statement of ingredients in

descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as ``skim milk'' or ``nonfat milk''.

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as ``milk''.

(5) Bacterial cultures may be declared by the word ``cultured'' followed by the name of the substrate, e.g., ``made from cultured skim milk or cultured buttermilk''.

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, and dried sweetcream buttermilk may be declared as ``buttermilk''.

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as ``whey''.

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as ``cream''.

(9) Butteroil and anhydrous butterfat may be declared as ``butterfat''.

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as ``eggs''.

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as ``egg whites''.

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(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as ``egg yolks''.

(13) [Reserved]

(14) Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., ``beef fat'', ``cottonseed oil'') in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the foods as ``------ shortening'' or ``blend of ------ oils'', the blank to be filled in with the word ``vegetable'', ``animal'', ``marine'', with or without the terms ``fat'' or ``oils'', or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., ``vegetable oil shortening (soybean and cottonseed oil)''. For products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the name shall include the term hydrogenated, or if partially hydrogenated, the name shall include the term partially hydrogenated. If each fat and/or oil in a blend or the blend is completely hydrogenated, the term ``hydrogenated'' may precede the term(s) describing the blend, e.g., ``hydrogenated vegetable oil (soybean, cottonseed, and palm oils)'', rather than preceding the name of each individual fat and/or oil; if the blend of fats and/or oils is partially hydrogenated, the term ``partially hydrogenated'' may be used in the same manner. Fat and/or oil ingredients not present in the

product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', ``contains one or more of the following:'', e.g., ``vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)''. No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in this paragraph (b)(14).

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in Secs. 137.105, 137.200, 137.220 and 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is ``flour'', ``white flour'', ``wheat flour'', or ``plain flour''; the first ingredient designated in the ingredient list of durum flour is ``durum flour''; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is ``whole wheat flour'', ``graham flour'', or ``entire wheat flour''; and the first ingredient designated in the ingredient list of whole durum wheat flour is ``whole durum wheat flour''.

(16) Ingredients that act as leavening agents in food may be declared in the ingredient statement by stating the specific common or usual name of each individual leavening agent in parentheses following the collective name ``leavening'', e.g., ``leavening (baking soda, monocalcium phosphate, and calcium carbonate)''. The listing of the common or usual name of each individual leavening agent in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of leavening agents in the product, the listing of individual leavening agents need not be in descending order of predominance. Leavening agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as

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``or'', ``and/or'', ``contains one or more of the following:''.

(17) Ingredients that act as yeast nutrients in foods may be declared in the ingredient statement by stating the specific common or usual name of each individual yeast nutrient in parentheses following the collective name ``yeast nutrients'', e.g., ``yeast nutrients (calcium sulfate and ammonium phosphate)''. The listing of the common or usual name of each individual yeast nutrient in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of yeast nutrients in the product, the listing of the common or usual names of individual yeast nutrients need not be in descending order of predominance. Yeast nutrients not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', or ``contains one or more of the following:''.

(18) Ingredients that act as dough conditioners may be declared in the ingredient statement by stating the specific common or usual name of each individual dough conditioner in parentheses following the collective name ``dough conditioner'', e.g., ``dough conditioners (L-cysteine, ammonium sulfate)''. The listing of the common or usual name of each dough conditioner in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of dough conditioners in the product, the listing of the common or usual names of individual dough conditioners need not be

in descending order of predominance. Dough conditioners not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', or ``contains one or more of the following:''.

(19) Ingredients that act as firming agents in food (e.g., salts of calcium and other safe and suitable salts in canned vegetables) may be declared in the ingredient statement, in order of predominance appropriate for the total of all firming agents in the food, by stating the specific common or usual name of each individual firming agent in descending order of predominance in parentheses following the collective name ``firming agents''. If the manufacturer is unable to adhere to a constant pattern of firming agents in the food, the listing of the individual firming agents need not be in descending order of predominance. Firming agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', ``contains one or more of the following:''.

(20) For purposes of ingredient labeling, the term sugar shall refer to sucrose, which is obtained from sugar cane or sugar beets in accordance with the provisions of Sec. 184.1854 of this chapter.

(21) [Reserved]

(22) Wax and resin ingredients on fresh produce when such produce is held for retail sale, or when held for other than retail sale by packers or repackers shall be declared collectively by the phrase ``coated with food-grade animal-based wax, to maintain freshness'' or the phrase ``coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness'' as appropriate. The terms ``food-grade'' and ``to maintain freshness'' are optional. The term lac-resin may be substituted for the term shellac.

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as ``water'' in the ingredient statement.

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(d) When foods characterized on the label as ``nondairy'' contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term ``nondairy'' on a creamer that contains sodium caseinate, it shall include a parenthetical term such as ``a milk derivative'' after the listing of sodium caseinate in the ingredient list.

(e) If the percentage of an ingredient is included in the statement of ingredients, it shall be shown in parentheses following the name of the ingredient and expressed in terms of percent by weight. Percentage declarations shall be expressed to the nearest 1 percent, except that where ingredients are present at levels of 2 percent or less, they may be grouped together and expressed in accordance with the quantifying guidance set forth in paragraph (a)(2) of this section.

(f) Except as provided in Sec. 101.100, ingredients that must be declared on labeling because there is no label for the food, including foods that comply with standards of identity, shall be listed

prominently and conspicuously by common or usual name in the manner prescribed by paragraph (b) of this section.

(g) When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word ``Ingredients,'' unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with Sec. 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words ``Other ingredients.'' Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in Herbs of Commerce, 1992 edition, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, 4733 Bethesda Ave., suite 345, Bethesda, MD 20814, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 Capital St. NW., suite 700, Washington, DC. The listing of these names on the label shall be followed by statements of:

(1) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., ``Garlic bulb'' or ``Garlic (bulb)''), except that this designation is not required for algae. The name of the part of the plant shall be expressed in English (e.g., ``flower'' rather than ``flos'');

(2) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: Herbs of Commerce for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the International Code of Botanical Nomenclature and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence. The International Code of Botanical Nomenclature (Tokyo Code), 1994 edition, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the International Code of Botanical Nomenclature may be obtained from Koeltz Scientific Books, D-61453 Konigstein, Germany, and University Bookstore, Southern Illinois University, Carbondale, IL 62901-4422, 618-536-3321, FAX 618-453-5207, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington DC.

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(3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

[42 FR 14308, Mar. 15, 1977, as amended at 43 FR 12858, Mar. 28, 1978; 43 FR 24519, June 6, 1978; 48 FR 8054, Feb. 25, 1983; 55 FR 17433, Apr.

25, 1990; 58 FR 2875, Jan. 6, 1993; 62 FR 49847, Sept. 23, 1997; 62 FR 64634, Dec. 8, 1997]

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
June 10, 1996

NOTICE TO MANUFACTURERS

Label Declaration of Allergenic Substances in Foods

This letter is to make you aware of the Food and Drug Administration's (FDA's) concerns regarding the labeling of foods that contain allergenic substances. Recently, FDA has received a number of reports concerning consumers who experienced adverse reactions following exposure to an allergenic substance in foods. These exposures occurred because the presence of the allergenic substance in the food was not declared on the food label.

The Food, Drug, and Cosmetic Act (the act) requires, in virtually all cases, a complete listing of all the ingredients of a food. Two of the very narrow exemptions from ingredient labeling requirements appear to have been involved in a number of the recent incidents, however. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, FDA regulations (21 CFR 101.100(a)(3)) exempt from ingredient declaration incidental additives, such as processing aids, that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food.

In some of the instances of adverse reactions, failure to declare an ingredient appears to have been the result of a misinterpretation of the exemption from ingredient declaration provided for incidental additives in 101.100(a)(3). FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of 101.100(a)(3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food. Thus, incidental additives may include substances that are present in a food by virtue of their incorporation as an ingredient in another food. However, when an ingredient added to another food continues to have an effect in the finished food (e.g., egg white as a binder in breading used on a breaded fish product), the ingredient is not an incidental additive, and its use must be declared on the label.

The recent adverse reaction reports indicate that some manufacturers have also incorrectly interpreted what constitutes an insignificant level of a substance. Clearly, an amount of a substance that may cause an adverse reaction is not insignificant. 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. Thus, it follows that the requirements of 101.100(a)(3) can not be met under such circumstances.

FDA is considering whether it is necessary to clarify its regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared and to ensure that sensitive individuals are protected by appropriate labeling.

We have also received reports of adverse reactions to foods in which likely allergenic substances were used as flavors, and not declared by name. Therefore, in addition to the exemption in 101.100(a)(3), the agency is also considering whether an allergenic ingredient in a spice, flavor, or color should be required

to be declared, 403(i) not withstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance, e.g., FD&C Yellow No. 5. The agency is open to suggestions on how to best address this problem.

While FDA has not formally defined "allergens," it provided examples of foods that are among the most commonly known to cause serious allergenic responses, i.e., milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans), in a policy statement dealing with foods derived from new plant varieties published in the FEDERAL REGISTER of May 29, 1992 (57 FR 22984 at 22987).

FDA advises that the issue of declaring allergenic ingredients in food is being discussed on an international level. Several individual governments and the Codex Alimentarius Commission have begun to formulate policy for the labeling of foods containing allergenic ingredients to ensure that consumers are provided sufficient information to avoid substances to which they are allergic. While packaged foods sold in the U.S. are among the most comprehensively labeled foods in the world (some countries provide broader exemptions from ingredient declaration), FDA is studying its labeling requirements, and considering whether rulemaking is necessary, for the labeling of allergenic ingredients.

While the agency does so, FDA asks manufacturers to examine their product formulations for ingredients and processing aids that contain known allergens that they may have considered to be exempt from declaration as incidental additives under 101.100(a)(3), and to declare the presence of such ingredients in the ingredient statement. Where appropriate, the name of the ingredient may be accompanied by a parenthetical statement such as "(processing aid)" for clarity.

The voluntary declaration of an allergenic ingredient of a color, flavor, or spice could be accomplished by simply naming the allergenic ingredient in the ingredient list. Because such ingredients are normally present at very low levels, the name of the ingredient could generally be placed at the end of the ingredient list and be consistent with its descending order of predominance by weight. Other, non-allergenic ingredients t hat are exempt from declaration would remain unlisted.

Another area of concern is the potential, inadvertent introduction of an allergenic ingredient to a food (e.g., in a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, where traces of peanuts, or peanut products, may end up in the product that does not normally contain peanuts). FDA is considering options for providing consumers with information about the possible presence of allergens in these foods.

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert name of allergenic ingredient)." FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP. The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food. The agency is open to suggestions on how best to address this issue.

Sincerely,

Fred R. Shank, Ph.D.

Director, Center for Food Safety and Applied Nutrition

This document was issued on June 10, 1996.
For more recent information on Food Labeling
See http://www.cfsan.fda.gov/label.html

Food Labeling

Foods Home | FDA Home | Search/Subject Index | Disclaimers & Privacy Policy | Accessibility/Help

Hypertext updated by lrd/dms/ear/kwg/cjm 2001-JUN-22

Compliance Policy Guide

Compliance Policy Guidance for FDA Staff

Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens[1]

This update to the Compliance Policy Guides Manual (August 2000 edition) is a new CPG. This update will be included in the next printing of the Compliance Policy Guides Manual. The statements made in the CPG are not intended to create or confer any rights for, or obligations on FDA or any private person, but are intended for internal guidance.

BACKGROUND:

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially involving the production of allergen specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label.

To combat this problem, the agency issued a letter titled "Notice to Manufacturers," dated June 10, 1996, which addressed labeling issues and Good Manufacturing Practices (GMPs). This letter is available on FDA's website, www.cfsan.fda.gov/~lrd/allerg7.html.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.[2, 3, 4]

Peanuts
Soybeans
Milk
Eggs
Fish
Crustacea
Tree nuts
Wheat

Note: For other foods that may cause an allergic response in certain individuals, the FDA district office should contact CFSAN/Office of Field Programs for guidance.

Manufacturers are responsible for ensuring that food is not adulterated or misbranded as a result of the presence of undeclared allergens. Therefore, the districts should pay particular attention to situations where these substances are added intentionally to food, but not declared on the label, or may be unintentionally introduced into a food product and consequently not declared on the label. When an allergen, not formulated in the product, is identified as likely to occur in the food due to the firm's practices, (e.g., use of common equipment, production scheduling, rework practices) then the district should determine if a manufacturer has identified and implemented control(s) to prevent potential allergen cross-contact, e.g. dedicated equipment, separation, production scheduling, sanitation, proper rework usage (like into like).

POLICY:

Direct addition as ingredients or sub-ingredients

Products which contain an allergenic ingredient by design must comply with 21 U.S.C. 343(i)(2). Where substances that are, bear, or contain allergens are added as ingredients or sub-ingredients (including rework), the Federal Food, Drug, and Cosmetic Act (the Act) requires a complete listing of the food ingredients (section 403(i)(2); 21 U.S.C. 343(i)(2); 21 C.F.R.101.4) unless a labeling exemption applies.

Exemptions from Ingredient Labeling

Section 403(i)(2) of the Act provides that spices, flavors, and certain colors used in a food may be declared collectively without naming each one. In some instances, these ingredients contain sub-components that are allergens.[5]

FDA's regulations (21 CFR 101.100(a)(3)), provide that incidental additives, such as processing aids, which are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food are exempt from ingredient declaration. Some manufacturers have asserted to FDA that some allergens that are used as processing aids qualify for this exemption. FDA, however, has never considered food allergens eligible for this exemption. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts; therefore, the presence of an allergen must be declared in accordance with 21 CFR 101.4. The exemption under 21 CFR 101.100(a)(3) does not apply to allergenic ingredients.

Practices Used to Prevent Potential Allergen Cross-contact

Allergens may be unintentionally added to food as a result of practices such

as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances may be insanitary conditions that may render the food injurious to health and adulterate the product under section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)].

REGULATORY ACTION CRITERIA:

The following represents criteria for direct reference seizure to the Division of Compliance Management and Operations (HFC-210):

1. The FDA district office obtains inspection evidence showing that a food was manufactured to contain an allergenic ingredient as a primary or secondary ingredient, but the food's label does not declare such allergenic ingredient,

and

2. The allergenic ingredient is one of the eight (8) ingredients listed in this guide,

and

3. The allergenic ingredient was not used as a processing aid in the production of the food,

and

4. The inspection of the firm was conducted consistent with the Guide To Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients.

The following represents the criteria for recommending legal action to CFSAN/Office of Field Programs/Division of Enforcement and Programs (HFS-605):

1. The food contains an undeclared allergenic ingredient that is a derivative of one of the eight (8) ingredients listed in this guide.
2. The food contains an undeclared allergenic ingredient that was used as a processing aid in the manufacture of the product.
3. The food contains an undeclared allergenic ingredient, but the ingredient is not one of the eight (8) allergens listed in this guide.
4. The food is not labeled as containing an allergen, but inspection of the firm shows that it was manufactured under conditions whereby the food may have become contaminated with an allergen.
5. The inspection of the firm was conducted consistent with the Guide To Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients.

Specimen Charges:

Misbranding due to an undeclared allergen:

The article was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 343(i)(2), in that it is fabricated from two or more ingredients, and its label fails to bear the common or usual name of each such ingredient, namely (specify the undeclared allergenic ingredient).

Adulteration due to food contamination with an allergen:

The article was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 342(a)(4), in that it has been prepared, packed and held under insanitary conditions whereby it may have been rendered injurious to health.

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1. This update to the Compliance Policy Guides Manual (August 2000 edition) is a new CPG. This update will be included in the next printing of the Compliance Policy Guides Manual. The statements made in the CPG are not intended to create or confer any rights for, or obligations on FDA or any private person, but are intended for internal guidance. [Back to ref.]

2. Food and Agriculture Organization of the United Nations, Report of the FAO Technical Consultation on Food Allergies. Rome, Italy, November 13 to 14, 1995. [Back to ref.]

3. Hefle, S.L., et al. Allergenic Foods. Critical Reviews in Food Science and Nutrition, 36 (S);S69-S89 (1996). [Back to ref.]

4. Sampson, H.A. Food Allergy, JAMA (278), pp.1888-1894, 1997. [Back to ref.]

5. As noted in the 1996 letter, FDA is exploring whether allergenic ingredients in spices, flavorings, or colors should be declared, 21 U.S.C. 343(i) notwithstanding. In the meantime, FDA strongly encourages the declaration of an allergenic ingredient of a spice, flavor, or color by either:

- declaring the allergenic ingredient by it's common or usual name in the ingredient list as a separate ingredient or parenthetically following the term spice, flavor, or color

  or

- as a declaration attached at the end of the list of ingredients indicating the presence of a specific allergen. [Back to ref.]

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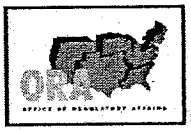

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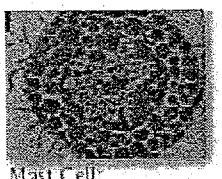

Mast Cell:
an immune cell activated in allergic reactions

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Borrelia burgdorferi
the bacterium that causes Lyme disease

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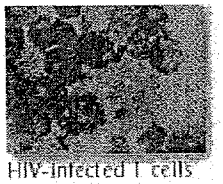

HIV-infected T cells

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Shingles Prevention Study

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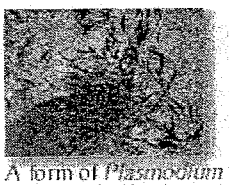

A form of *Plasmodium* the parasite that causes malaria

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Last updated August 31, 2001 (idr)

Incoming

DEBORAH JENNETTE ALEXANDER

April 3, 2001

Secretary Tommy Thompson
The US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

I am writing to you because I am a 22 year old woman and I have had many allergic reactions where I have had to go to the hospital since I have been 16. While I am not trying to gain your sympathy, I am not eager for my allergic reactions to continue and I am wondering if you could ask the Senate Health, Education, Labor and Pensions Committee or the National Institute for Allergy and Infectious Diseases at the NIH to study severe allergy reactions.

I have had allergic reactions to yellow jackets, soy, sesame and peanuts. My primary concern is my allergy to soy, sesame and peanuts. Currently there is no cure for my food allergies, except for strict avoidance. While I abide by the principle of strict avoidance, there is no way that I can avoid the scent of soy, sesame and peanuts when my peers and colleagues choose to eat them. Just like a person who suffers from Hay Fever suffers from the scent of pollen, I react to the scent of soy, sesame and peanuts.

In addition to studying and trying to find a cure for food allergies, I am wondering if the system of labeling food can be changed to the benefit of food allergic individuals. Currently it appears that individual food manufacturers have the discretion of labeling their products to alert food allergic individuals. Since more people are becoming aware about the peanut allergies in particular and other food allergies, I am wondering if you can require all food manufacturing companies to add a label similar to the Surgeon General's warning for cigarette smoke to all packages. The label would explain to food allergy consumers that the product may contain peanuts, or other food that may be harmful to a person's health. In addition, I am wondering if you could also require all restaurants to add a large label to their menus stating which food contains peanuts or other food. I know that food manufactures are not required to mention ingredients in food if it is makes up less than 2% of the product. However, less than 2% in a food can be extremely harmful to allergic individual. I am requesting that all products be labeled: if there is more and less than 2% of any ingredient in food.

I hope that you will seriously consider my letter. I am very interested in working with you to make life better for all food allergy sufferers. My contact information is below.

Sincerely,

Deborah J Alexander

Deborah J. Alexander

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