DEPARTMENT OF H

Ms. Heidi Hag
565 South Roa
Belmont, Cali

Dear Ms. Hagl

Thank you for

exemptions from these ingredient-labeling requirements. First, section 403(i) of the FD&C Act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Second, FDA regulations (Title 21, Code of Federal Regulations (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 other words, when an ingredient is used during processing or is added as a secondary ingredient, and is present at insignificant levels and has no technical or functional effect in the finished food, the ingredient may not be required to be declared in ingredient labeling. However, in a 1996 Notice to Manufacturer's (copy enclosed), FDA clarified that certain foods, including nuts, could not be considered incidental additives because of their allergenic potential.

We would like to point out that manufacturers are responsible for ensuring that foods they produce are safe. FDA has issued regulations called Good Manufacturing Practices (GMPs) to prevent contamination of foods during the manufacturing process so that the food is not harmful to consumers. Manufacturers must follow GMPs to ensure that no allergen is inadvertently introduced into the product. Nevertheless, because we recognize that the presence of allergens in food may be life threatening, we have been focusing increased attention and activities on issues related to food allergens, especially the control of allergens in products not intended to contain allergens and the proper labeling of products containing allergens.

In our continuing efforts to address allergens, FDA recently issued two food allergen guidance documents. FDA issued the Allergen Inspection Guide to FDA field offices on April 9, 2001. The Allergen Inspection Guide provides field investigators and inspectors with specific guidance on inspection methods, techniques, procedures, and policy relating to allergenic ingredients. On May 3, 2001, the Agency published a Compliance Policy Guide (CPG) on Allergens, entitled, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens[1]" (copy enclosed). This CPG provides guidance to the Agency's compliance staff, field investigators, and the regulated industry on Agency policy and regulatory action criteria for undeclared food allergens.

The Agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert the name of allergenic ingredient)" as a precautionary measure if they cannot ensure that the product does not contain the allergenic ingredient. FDA has advised manufacturers that, because adhering to GMPs is essential for effective reduction of adverse reactions, such advisory labeling should not be used in place of adherence to GMPs. The Agency has urged manufacturers to take all steps necessary to eliminate cross contact and to ensure the absence of the allergenic food before relying on "may contain" labeling to protect the consumer. Even with GMP regulations in place, the Agency is still considering how best to alert sensitive consumers to the unintentional introduction of allergens into food since its presence would not be declared in the ingredient statement.

In addition to FDA activities, industry has also been working to develop voluntary programs to reduce the incidence of undeclared allergens in food products. The Food Allergy Issues Alliance, which includes representatives from industry, trade associations, a consumer group, and academia, submitted a consensus document on guidelines for food allergen labeling to FDA. The Food Allergy Issues Alliance asserted that the guidelines would address food allergen issues their member companies could immediately implement without requiring FDA to amend or promulgate regulations. Additionally, the National Food Processors Association has developed a pamphlet for its members to describe general practices that can ensure effective strategies for managing food allergens.

Because FDA recognizes that the labeling of food allergens is a concern of allergic consumers and additional measures may be needed to ensure that consumers obtain adequate information about the foods they eat, we will hold a public meeting on August 13, 2001, to obtain input from the public on allergen labeling issues to determine what additional actions may be necessary to assist consumers in identifying products containing allergens and to assist manufacturers in producing food products that are safe for allergenic consumers. Specifically, the meeting will focus on: (1) source labeling or plain English labeling; (2) advisory labeling such as "may contain nuts," and (3) labeling of flavorings, spices, and

colors and of incidental additives. A Federal Register Notice that provides additional information about this meeting is enclosed.

We also have 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.

Thanks again for your letter to Senator Boxer and for your interest in FDA's food labeling activities. We hope this information is helpful.

Sincerely,

Kristina Harper

for Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures

cc: The Honorable Barbara Boxer
United States Senate
Washington, D.C. 20510-0505

Dockets Management Branch, HFA-305
(Docket No. 00P-1322)

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

Home

Hypertext updated by lrd/dms/ear 2000-JAN-31

Office of Regulatory Affairs
Compliance References:
CPG - Chapter 5 - Foods, Colors and Cosmetics

CPG Contents:

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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[Federal Register: July 25, 2001 (Volume 66, Number 143)]
[Proposed Rules]
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[DOCID:fr25jy01-29]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00P-1322]

Food Safety and Food Labeling; Presence and Labeling of Allergens in Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the labeling of food products containing allergens. The purpose of the meeting is to stimulate discussion and to obtain information to help FDA determine what additional actions may be necessary to provide consumers with adequate information on product labels. The meeting will focus on: Source or plain English labeling; advisory labeling (e.g., ``May contain [name of food allergen]''); and labeling of ingredients exempted from declaration (common or usual names of flavorings, spices, and colors; incidental additives).

DATES: The public meeting will be held on August 13, 2001, from 9 a.m. to 4 p.m. Please preregister by close of business on August 6, 2001. Preregistered persons should check in before the meeting between 8:30 a.m. and 9 a.m. Late registration will be accepted contingent on space availability. Comments must be submitted no later than October 29, 2001.

ADDRESSES: The meeting will be held at the Cohen Bldg., 330 Independence Ave. SW., Washington, DC 20201, 202-619-1299 (Metro: Federal Center SW.). All attendees must enter the building at the Independence Ave. entrance.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: FDADOCKETS@oc.fda.gov, or at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm.

FOR FURTHER INFORMATION CONTACT:

For registration: Please register by close of business on August 6, 2001, electronically at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Once on this Internet site, select Docket No. 00P-1322 (Food Labeling and Allergen Contamination Control) and follow the directions. You may also register by mail at Dockets Management Branch (address above).

For registration information: Ayesha Weaver, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 200 C

St. SW., Washington, DC 20204, 202-205-3587, FAX 202-205-5295.

For general information: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4168, FAX 202-205-5295.

SUPPLEMENTARY INFORMATION:

I. Background

Each year FDA receives reports of consumers who experience adverse reactions following exposure to allergenic substances in foods. Food allergies are abnormal responses of the immune system, especially the production of allergen-specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Most consumers are aware of their specific sensitivities and rely on the food label to avoid foods that might result in an allergenic reaction. However, adverse reactions often occur when an allergen-sensitive consumer consumes an allergenic substance that has not been declared on the food label.

Section 403 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343) requires food labels to bear a complete listing of all the ingredients in a food. This permits consumers to obtain accurate information about the foods that they eat by reading the ingredient list. However, the act and FDA's regulations provide two narrow exemptions from the ingredient labeling requirement. First, section 403(i) of the act provides that flavorings, spices, and colors may be declared collectively without naming each one. In some instances, these collective ingredients contain subingredients that are allergens. (FDA is exploring whether allergenic ingredients in spices, flavorings, or colors should be declared, section 403(i) of the act notwithstanding.) Second, FDA regulations exempt incidental additives (e.g., processing aids) from ingredient declaration if they are present in a food at insignificant levels and do not have a technical or functional effect in the finished product (Sec. 101.100(a)(3) (21 CFR 101.100(a)(3))). Thus, in some cases

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food labels may not provide consumers with food allergies with information about all the ingredients that are in the foods that they eat.

In addition to exemptions for ingredient labeling, there are other ways in which consumers may inadvertently come in contact with allergenic substances. For instance, some consumers may be unaware of the allergenic source of ingredients declared by their common or usual names in the ingredient statement. For example, consumers may not understand that the source of the ingredients ``whey'' and ``casein'' is ``milk,'' which is a common food allergen. Another area of concern is the potential, inadvertent introduction of an allergenic ingredient to a food (e.g., cross-contact during manufacturing where traces of peanuts end up in a product that does not normally contain peanuts because the product is manufactured on the same production line as a product containing peanuts).

The undeclared presence of allergens in foods is a serious public health issue because the ingestion of food allergens is potentially life-threatening to sensitive individuals. Therefore, as part of its public health mission to keep food safe, FDA has been focusing increased attention and activity on issues relating to food allergens, especially the proper labeling of products containing such allergens and the control of food allergens in products not intended to contain such allergens.

Currently, the only successful method to manage food allergy is avoidance of foods containing the allergen. FDA's allergen awareness

efforts are currently focused on the eight foods that are most frequently implicated in serious allergic responses: (1) Peanuts; (2) soybeans; (3) milk; (4) eggs; (5) fish; (6) crustacea (e.g., lobster, crab, shrimp); (7) tree nuts (e.g., almonds, chestnuts, macadamia nuts, pecans, walnuts, hazelnuts or filberts, cashews, brazil nuts, pistachios, pine nuts); and (8) wheat.

There has been growing activity surrounding food allergens. The number of allergen-related food recalls increased steadily since 1990. Further, FDA has received correspondence from consumers, as well as from members of Congress (on behalf of their constituents) expressing concern about undeclared allergens in foods. FDA has also received a citizen petition requesting agency action to address food allergens (Docket No. 99P-2148). Similarly, in May of 2000, the attorneys general of nine States expressed their concern about food allergens and submitted a petition asking FDA to amend its regulations on food labeling and manufacturing practices (Docket No. 00P-1322).

In response to food allergy concerns, the Food Allergy Issues Alliance (a private group comprised of industry and trade group representatives and a consumer group, as well as a scientific advisor representing academia) recently submitted (May 2001) a consensus document on guidelines for food allergen labeling (Ref. 1). The Food Allergy Issues Alliance asserted that the guidelines would address food allergen issues their member companies would be implementing soon without requiring FDA to amend or issue regulations.

FDA replied to their submission (Refs. 2, 3, and 4) stating that the agency considered the guidelines a significant step forward in addressing the prevalence and identification of the eight most common food allergens in plain, simple language. The agency also indicated it was pleased that the document recognized the public health need to disclose food allergens. FDA finally noted that the Food Allergy Issues Alliance guidelines laid the groundwork for addressing additional food allergen issues in the future. The agency finds the guidelines consistent with both our positions on food allergens (as articulated in the past) and with the purpose behind the public meeting, as described later in this document, and therefore is an appropriate starting point for discussions at the public meeting.

FDA's concern about food allergens has prompted several agency actions, most notably a notice to manufacturers on the label declaration of allergens (1996), an FDA/State partnership to increase industry's understanding of allergens and to identify effective manufacturing controls (1998), and issuance of food allergen guidance documents (2001). Information on these initiatives is available at the FDA Web site on allergens at http://www.cfsan.fda.gov/dms/wh-alrgy.html.

II. Public Meeting--August 13, 2001

FDA is announcing a public meeting on August 13, 2001, to explore certain allergen-related labeling issues in greater detail. The meeting is intended to aid the agency in determining what additional actions may be warranted to further assist consumers with food allergies in identifying products containing food allergens and to assist manufacturers in producing foods that are safe for consumers with food allergies.

The agency is requesting written and oral comments in three topic areas relating to food allergens within the context outlined above: (1) Source or plain English labeling; (2) advisory labeling (e.g., ``May contain [name of food allergen]''); and (3) labeling of ingredients exempted from declaration (common or usual names of flavorings, spices, and colors; incidental additives). Recommendations from the petition submitted by the attorneys general of nine States (Docket No. 00P-1322) and the allergen-labeling guidelines from the Food Allergy Issues Alliance (Ref. 1) are incorporated into the discussion of the three topic areas, as appropriate.

A. Source or Plain English Labeling

FDA recognizes that many of the common or usual names for ingredients listed in the ingredient statement are not understood by consumers to be derived from food allergens (e.g., ``caseinate'' or ``whey'' derived from ``milk'' and ``albumin'' derived from ``egg''). FDA is considering whether additional labeling of food products is necessary in some instances to ensure that allergenic consumers are informed about the presence of food allergens.

FDA is considering how best to make source or plain English labeling more widely available to consumers so that the labels will be more understandable. To assist the agency in its deliberations, FDA is asking several questions relating to source labeling:

1. What plain English terms would be understandable for the eight most common food allergens?

2. What source or plain English labeling format or formats would be most informative to consumers? Are the formats from the Food Allergy Issues Alliance appropriate and sufficient? Are the recommendations in the petition from the attorneys general of nine States warranted and beneficial? Are multiple formats confusing to consumers, and if so, is there a single format that would be preferable? If so, why?

3. Should source or plain English labeling be voluntary or mandatory for the eight most common food allergens?

B. Advisory Labeling (e.g., ``May contain [name of food allergen]'')

Advisory labeling includes statements such as ``may contain peanuts'' or ``made on shared equipment'' on food packaging labels. FDA's current position is that advisory labeling should not be used in lieu of adherence to good manufacturing practices (GMPs) because adhering to GMPs is essential for effective reduction of adverse reactions. Food that contains an allergen due to cross-contact or other contamination may be considered adulterated under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)) because it has been prepared, packed, or held under insanitary

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conditions that may render the food injurious to health. Thus, FDA believes advisory labeling should not be the norm, and manufacturers should strive to eliminate the presence of allergenic materials that are not intentionally added to a specific food product.

However, FDA recognizes that advisory labeling is an attempt by manufacturers to inform consumers of the possibility that cross-contact may have occurred such that the product contains an allergenic substance. FDA is considering whether, and if so, under what circumstances advisory labeling should be permitted when appropriate manufacturing controls are not sufficient to guarantee the absence of allergenic substances in a particular food product. If permitted, clear criteria will be needed to guide the use of such statements. Additionally, FDA is assessing whether advisory labeling is useful to consumers, how consumers interpret advisory labeling statements, and what wording would be most understandable. To help the agency better understand if there is a need for advisory labeling, when it would be appropriate, how such statements would be used by consumers, and what wording would be most helpful to the consumer, the agency asks the following questions:

1. Under what circumstances, if any, should advisory labeling statements (e.g., ``May contain [name of allergen]'') be permitted, and what impact would those circumstances have on manufacturers and on consumers? Should the recommendations in the petition from the attorneys general of nine States be adopted? Do the criteria from the Food Allergy Issues Alliance form a reasonable basis for determining

when a manufacturer may use advisory labeling on a particular product or should other criteria be used? Why?

2. Are there better alternatives for advisory labeling than the type of wording that currently exists (e.g., ``May contain [name of specific allergen],'' ``Made on shared equipment,'' ``Manufactured in a facility that also processes [name of specific allergen]'')? Do such statements adequately inform consumers of possible cross-contact with allergenic materials? How do consumers interpret the wording of such labeling? Should advisory labeling statements be prescriptive (i.e., one or more specific statements) or flexible?

3. Where should advisory labeling statements be located on the food label? How prominent should advisory labeling statements be on the label? Should the location and prominence of advisory labeling statements be prescribed?

C. Labeling of Ingredients Exempted From Declaration (Common or Usual Names of Flavorings, Spices, and Colors; Incidental Additives)

1. Common or Usual Names of Flavorings, Spices, and Colors

As previously noted, the collective naming of flavors, spices, and certain colors is one of the exemptions to the requirement for the complete labeling of ingredients (section 403(i) of the act). This exemption permits these ingredients to be listed collectively in the ingredient statement (e.g., ``Ingredients: * * *flavorings * * *'') without naming each by its common or usual name. Food labels with collectively named flavorings, spices, and colors may not adequately inform individuals who wish to avoid allergenic substances, particularly when the allergenic substance is not specifically identified.

FDA believes that the declaration of allergenic ingredients in individual flavorings, spices, and colors is necessary for consumers to adequately protect themselves from exposure to food allergens. On a case-by-case basis, FDA has used notice-and-comment rulemaking to require the declaration of individual allergenic flavorings, spices, and colors. This is a labor-intensive and time-consuming process for the agency.

FDA is considering whether continuing to address allergenic flavorings, spices, and colors on a case-by-case basis is the best approach available to the agency. The petition from the attorneys general of nine States (Docket No. 00P-1322) recommended 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 (e.g., peanut flavoring). The allergen-labeling guidelines from the Food Allergy Issues Alliance (Ref. 1) advocated additional voluntary disclosure of food allergens that are intentionally part of foods, including substances exempted from labeling by regulations (e.g., flavorings). Questions for the public meeting relate to the alternatives available to the agency:

1. Should the agency continue to address the labeling of individual allergenic flavorings, spices, and colors on a case-by-case basis, or should there be a generally applicable policy?

2. Should the information on allergenic components of flavorings, spices, and colors be included in the ingredient list? Is there a better location or format for this information? Explain.

3. For individual flavorings, spices, or colors that contain one of the eight most common allergens, should listing the common or usual name of the individual flavoring, spice, or color on the product labeling be voluntary or mandatory?

2. Labeling of Incidental Additives

Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food have been exempted by regulation from labeling on an ingredient statement (Sec. 101.100(a)(3)). Incidental additives include substances that have no technical or functional effect in the finished product,

processing aids, and substances that may migrate to the food from equipment or packaging. FDA has stated that because very small amounts of some allergenic substances can cause serious allergic responses, allergens that cause serious allergic reactions cannot be considered to be present at an ``insignificant'' level in the food. The agency has stated that all allergenic substances introduced as ingredients or as the result of manufacturing processes do not qualify as incidental additives and must be declared in the ingredient statement on the label of a food product (Ref. 5).

With regard to incidental additives, FDA understands that the main difficulty is that manufacturers may be unaware that a particular minor ingredient or processing byproduct may be allergenic and therefore must be declared on product labels. The petition from the attorneys general of nine States (Docket No. 00P-1322) recommended amending the regulations for ingredients that are derived from one of the eight most common allergenic substances to specify that such ingredients may not be considered incidental additives under Sec. 101.100(a)(3) and must be declared on the product label. The allergen-labeling guidelines from the Food Allergy Issues Alliance (Ref. 1) suggested that food companies follow FDA's current guidance regarding the labeling of ``incidental ingredients'' that are or that contain one of the eight most common food allergens by declaring the allergen in the ingredient list of the food. The questions for the public meeting relate to gathering information and exploring educational alternatives to increase manufacturer understanding:

1. What, if any, minor ingredients would manufacturers be unlikely to recognize as containing food allergens and therefore not include on the label, and what kinds of manufacturing processes would manufacturers be unlikely to recognize as inadvertently introducing food allergens?

2. When products that contain food allergens will be further processed or

[[Page 38594]]

repacked, is food allergen labeling sufficient on such intermediate products or is it necessary to have clearer labeling on intermediate products to ensure that food allergens are appropriately declared on the retail packaging of the final product?

3. Should the agency 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?

III. Summary

FDA's public meeting, scheduled for August 13, 2001, is intended to help the agency determine what additional actions may be warranted to provide consumers with adequate food allergen information on product labels. FDA recognizes that there are additional food allergen areas that may need to be addressed at future meetings or through agency actions, e.g., food handling practices and providing food allergen information in restaurant settings. However, at this time, the agency is focusing on issues relating to labeling and manufacturing of the eight most common food allergens; therefore, the public meeting will be restricted to discussion of the topic areas described above.

IV. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, you must preregister in writing by close of business on August 6, 2001, either electronically or by mail (information above). You must provide your name, title, business affiliation (if applicable), address, telephone number, fax number, e-mail address, and the type of organization you represent (e.g., industry, consumer organization).

Preregistered persons should check in before the meeting between 8:30 a.m. and 9 a.m. Persons who have not preregistered may register before the meeting between 8:30 a.m. and 9 a.m., dependent on space availability. All attendees must enter the building at the Independence Ave. entrance. If you need special accommodations due to disability (e.g., sign language interpreter), please inform the contact person when you register.

If, in addition to attending, you wish to make an oral presentation during the meeting, you must indicate this on your registration form and submit: (1) A brief written statement of the general nature of the views you wish to present, and (2) the names and addresses of all persons who will participate in the presentation. Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation (from 3 to 5 minutes). If you decide at the meeting that you wish to make a comment, you must sign up at the registration desk, dependent on time availability. It is anticipated that, if time permits, persons attending the meeting will have the opportunity to ask questions during the meeting.

V. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the topics addressed at the public meeting on or before October 29, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

You may access a copy of the transcript on the FDA Web site at http://www.fda.gov, request a transcript of the meeting from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 20 working days after the meeting, at a cost of 10 cents per page, or examine a transcript of the meeting after September 10, 2001, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from Regina Hildwine, National Food Processors Association (NFPA), Lisa D. Katic, Grocery Manufacturers of America (GMA), and Anne Munoz-Furlong, Food Allergy and Anaphylaxis Network (FAAN), to Joseph A. Levitt, Center for Food Safety and Applied Nutrition (CFSAN), FDA, May 22, 2001.

2. Letter from Joseph Levitt, CFSAN/FDA, to Regina Hildwine of NFPA, May 30, 2001.

3. Letter from Joseph Levitt, CFSAN/FDA, to Lisa D. Katic of GMA, May 30, 2001.

4. Letter from Joseph Levitt, CFSAN/FDA, to Anne Munoz-Furlong of FAAN, May 30, 2001.

5. ``Compliance Policy Guide (CPG)--Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens'' http://www.fda.gov/ora/compliance--ref/cpg/cpgfod/cpg555-250.htm

VIII. Registration

REGISTRATION FORM--PUBLIC MEETING ON ALLERGENS IN FOODS

Instructions: Please register using this form by close of business on August 6, 2001, electronically at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Once on this Internet site, select Docket No. 00P-1322 (Food Labeling and Allergen Contamination Control) and follow the directions. You may also register by mail at Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 70852.

Name: _____

Title: _____

Organization: _____

Address: _____

Telephone: _____

FAX: _____

E-mail: _____

Please indicate the type of organization you represent:

Industry _____

Government _____

Consumer Organization _____

Media _____

Law Firm _____

Educational Organization _____

Other (specify) _____

Do you wish to make an oral presentation?

Yes _____

No _____

If yes, you must also submit the following:

1. A brief written statement of the general nature of the views you wish to present.

2. The names and addresses of all persons who will participate in the presentation.

Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation (from 3 to 5 minutes).

Dated: July 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-18617 Filed 7-23-01; 12:16 pm]

BILLING CODE 4160-01-S

BARBARA BOXER
CALIFORNIA

COMMITTEES:
COMMERCE, SCIENCE, AND TRANSPORTATION
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May 22, 2001

Ms. Melinda K. Plaisier
Associate Commissioner for Legislative Affairs
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857

Dear Ms. Plaisier:

I am forwarding to you a letter I received from one of my constituents.

I would appreciate it if you would look into this matter and respond to my constituent directly. Please also send me a copy of your response.

Thank you in advance for your consideration.

Sincerely,

Barbara Boxer

Barbara Boxer
United States Senator

BB:cms
Enclosure

1700 MONTGOMERY STREET
SUITE 240
SAN FRANCISCO, CA 94111
(415) 403-0100

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LOS ANGELES, CA 90012
(213) 894-5000

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600 'B' STREET
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201 NORTH 'E' STREET
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01-2723

Heidi Hagler
565 South Road
Belmont, CA
94002

Ms. Barbara Boxer
1700 Montgomery Street, Suite 240
San Francisco, CA
94111

5/5/01

Dear Ms. Boxer,

My six year old daughter, Hanna, was diagnosed with peanut and tree nut allergies when she was about two, after a life threatening incident in which she took a bite from another's child's PB&J. Since that incident, we have always carefully read the ingredients on the packaging of the food she was served.

In the meantime, she was also diagnosed with chronic otitis media due to fluid which was persistently behind her eardrums. The result was a 45% hearing impairment, and speech and language delays for which she is still receiving speech therapy. (Tubes were ultimately inserted into her eardrums that corrected her hearing, but the fluid still recurred on an intermittent basis).

As time marched on, we noticed that more and more foods were labeled as containing nuts or traces of nuts, which had not previously been so labeled. We also noticed that as we ceased giving Hanna the newly labeled nut containing foods, her allergy symptoms--- including the fluid behind her eardrums--- significantly diminished.

I was dismayed to learn from the enclosed article that the FDA does not *require* food manufacturers to indicate on the label that a food contains nut traces or was manufactured in a facility where other nut products are made. Apparently the industry prefers such standards to remain voluntary and the courts have not (yet) made the fear of liability an incentive to label foods accurately.

The problem with voluntary labeling is that when nuts aren't mentioned on the label, consumers don't know whether a product is "safe" or whether the manufacturer is simply

choosing not to comply with the voluntary standards. Here's an example: Mother's Circus Cookies (the pink and white frosted cookies that are shaped like animals), made right here in Northern California. To taste them and look at them, you would not think they contain nuts. Nuts are not mentioned anywhere on the label, and there is no information indicating that nut products are made in the same facility. After eating about three of the cookies, Hanna began to rub her eyes, which became watery. Her nose began to itch and run. On a hunch, I called the 800 number on the package. The customer service representative advised me that indeed these cookies are made on the same production line as nut-containing cookies. When I asked why this is not mentioned on the label, I was told, "Because we aren't required to, but I'll make the suggestion to our corporate headquarters."

I urge you to support legislation, which would *require* food makers test their products for allergins, and to label nuts as ingredients or contaminants. Foods produced outside of the U.S., which have not been tested for nuts/nut contamination should include a clear notice on the label stating such. Had this type of labeling been in place four years ago, my daughter might have avoided dozens of ear infections, thousands and thousands of dollars worth of speech therapy, and who knows how many potentially life-threatening exposures to nuts. Voluntary standards are inadequate. The presence of an 800 number such as Mother's Cookies' is also an insufficient approach: it essentially requires purchase of the product before you can go home to make the phone call.

Apparently there is also legislation under consideration, which would require food manufacturers to take steps to prevent contamination. Please also support this legislation, but in the absence of accurate labeling, we may not know whether manufacturers are successful in preventing contamination until it is too late for Hanna or somebody else equally vulnerable.

Thank you for your consideration of my concerns.

Sincerely,

Heidi Hagler

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www.nytimes.com
The New York Times ON THE WEB

April 3, 2001

F.D.A. Finds Faulty Listings of Possible Food Allergens

By GREG WINTER

An investigation of dozens of food companies by the Food and Drug Administration has found that in spite of strict labeling laws, as many as 25 percent of manufacturers failed to list common ingredients that can cause potentially fatal allergic reactions.

The mislabeling poses a threat to the roughly seven million Americans who suffer from food allergies and who rely on a product's packaging to keep them safe, according to the F.D.A.

In recent years, there has been a sharp increase in the amount of food recalled from store shelves for containing allergy- provoking ingredients like peanuts and eggs that were not listed on the product's label. Worried about the trend, the F.D.A. enlisted the support of state regulators in Minnesota and Wisconsin to undertake a series of inspections at food plants over the last two years, trying to grasp the extent of the problem and correct it at the source.

The agency examined 85 companies of all sizes that were likely to use common allergy triggers in abundance: cookie makers, candy companies and ice cream manufacturers. Its report, which was completed earlier this year, found that a quarter of the companies made products with raw ingredients like nuts, but omitted them from the labels describing the food.

Perhaps more surprising, only slightly more than half of the manufacturers checked their products to ensure that all of the ingredients were accurately reflected on the labels, the report said, making it all the more difficult for consumers to know which foods might cause allergic reactions that are often life-threatening.

"The fact that ingredient listings can be dead wrong certainly points to major shortfalls in food safety," said Caroline Smith DeWaal, food safety director at the Center for Science in the Public Interest. "The accuracy of a label can really save a life."

Although the cause of food allergies is still something of a mystery, they are the most common cause of anaphylaxis, a severe reaction in which the skin itches, the throat swells and breathing becomes short. In the most serious cases, blood pressure falls, the heart beat fluctuates and some victims die.

The F.D.A. report does not discuss the prevalence of food allergies, but every year, 30,000 people are rushed to emergency rooms because of them, according to the American Academy of Allergy, Asthma and Immunology. As many as 200 of them die.

Many of these illnesses occur at restaurants or in homes, and are not necessarily the fault of a food manufacturer. Some schools have removed peanut butter from their cafeterias and several airlines have taken steps to accommodate passengers who have food allergies, including banning peanuts as the traditional after-takeoff snack.

It is not clear how many allergic consumers have fatal reactions to mislabeled products, but even when they do, the manufacturer may not be liable for them. Last August, a Wisconsin jury ruled against the family of Joshua Ramirez, a 21-year- old junior at a bible college who had a lifelong allergy to peanuts and who died in 1996 after eating chocolate chip cookies from the vending machine in his dormitory.

During the trial, the company, **Slettin Vending** Inc., acknowledged that the cookies contained peanut residue, although the nuts did not appear on the list of ingredients.

Still, only a small amount of peanuts were found in the cookies. It may have been enough to provoke a fatal reaction in Joshua, the company concedes, but it was not sufficient for a jury to deem the product unreasonably dangerous to the average consumer. That is the standard of proof necessary in many product liability cases.

"People are convinced that with allergies you just get itchy, watery eyes," said Dixie G. Ramirez, Joshua's mother. "They do not believe they can be fatal."

After suffering an allergic reaction, consumers can be treated with a shot of epinephrine, and they are often encouraged to carry the drug with them. But there is no medical treatment to prevent allergic reactions to food from occurring. Even patients who receive epinephrine may need additional treatment, so clear and accurate labels may be the only thing standing between a susceptible consumer and a trip to the hospital.

As awareness of the problem grows, manufacturers say they are paying more attention to what goes into their products, but it is often difficult for them to know when ingredients that can provoke a reaction, called allergens, slip into the food chain undetected.

In fact, many of the "hidden" allergens found in the F.D.A. study were not deliberately added, but wound up in sweets because bakers routinely used the same utensils to stir separate mixes, or reused baking sheets without washing them between batches. Slettin, for example, used the same pan liners in its bakery from one day to the next.

In some factories, parchment papers were used as many as 10 times before being replaced, the F.D.A. found. In at least one plant, conveyor belts that coated candies in chocolate were cleaned only once a year, allowing peanut residue to get into products that as far as the manufacturer was concerned, contained nothing risky at all.

Such cross-contamination may seem incidental. But for people with food allergies, ingesting as little as one five-thousandth of a teaspoon of an allergen can induce a fatal reaction within minutes, according to Dr. Hugh A. Sampson, director of Mount Sinai School of Medicine's food allergy institute.

Current F.D.A. rules require companies to list everything that goes into their products, but allow trace amounts of "natural" ingredients to be omitted from labels.

To close those loopholes, a coalition of attorneys general in nine states, from New York to Wyoming, petitioned the F.D.A. last May to issue new regulations. If enacted, the new rules would require manufacturers to warn consumers that their products might contain allergens, even if they are not deliberately added as ingredients.

Turning the petition into new regulations could take years, since manufacturers would have ample opportunity to fight them. For now, the F.D.A. says it is having more success persuading the industry to make voluntary changes. In fact, the agency found that most of the companies it inspected were willing to overhaul their manufacturing.

But the F.D.A. cannot afford to visit all food companies, prompting some lawmakers to push for legislation with stricter standards. Representative Nita M. Lowey, Democrat of New York, has introduced legislation in Congress to require manufacturers to act to prevent unintentional contamination of products, something the law does not now require.

It also calls upon food companies to list allergens by their "common English" names. Even when they do appear on labels, many ordinary allergens are referred to by their formal names, like "casein" for milk or "albumin" for eggs.

"To the lay person, these terms are Greek," said Anne Muñoz-Furlong, founder of the Food Allergy and Anaphylaxis Network. "The labels are written for scientists, not for consumers."