installing spacers on the wiring support brackets and standoffs; installing a clamp next to the grommet at each tank unit; and replacing the clamp O-rings), in accordance with the Accomplishment Instructions of that service bulletin.

Replacement and Reporting of Damaged Wiring

(b) If any damaged wiring is found during the performance of the modifications required by paragraph (a)(1), (a)(2), or (a)(3) of this AD, before further flight, replace the damaged wiring with new wiring in accordance with Boeing Standard Wiring Practices Manual D6–54446, Chapter 20, Section 10, Subject 11 (20–10–11), dated August 1, 1996. Submit a report of damaged wire findings to the Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207, at the applicable time specified in paragraph (b)(1) or (b)(2) of this AD. The report must include a description of any discrepancies found, the airplane serial number, and the number of landings and flight hours on the airplane. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For airplanes on which the modifications are accomplished after the effective date of this AD: Submit the report within 14 days after performing the applicable modification required by paragraph (a)(1), (a)(2), or (a)(3) of this AD.

(2) For airplanes on which the modifications have been accomplished prior to the effective date of this AD: Submit the report within 14 days after the effective date of this AD.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 19, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–18473 Filed 7–24–01; 8:45 am]

BILLING CODE 4910–13–P

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 (§ 101.100(a)(3) (21 CFR 101.100(a)(3))). Thus, in some cases

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

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 (§ 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 § 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

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

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

Proposed Revisions of Freedom of Information Act Regulations and Implementation of Electronic Freedom of Information Act Amendments of 1996

AGENCY: National Labor Relations Board.