

We also require three new collections which are the primary focus of this supporting statement. First, we have added new § 489.20(u)(2) to require a hospital to require all physicians who are members of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member. The burden associated with this requirement is two-fold and pertains to both hospitals and physicians. First, hospitals are required to update by-laws and policies and procedures to reflect that as a condition of medical staff membership or admitting privileges, physicians must agree to disclose ownership or investment interests to patient. In addition, physicians are required to develop disclosure notices, distribute them to patients and maintain these disclosures in the patients' medical records.

Finally, we are including new language under § 489.20(v) to provide for an exception to the disclosure requirements for a physician-owned hospital that does not have at least one referring physician who has an ownership or investment interest in the hospital (or who has an immediate family member with an ownership or investment interest in the hospital), provided that the hospital attests, in writing, to that effect and maintains such attestation in its files. The burden associated with this requirement is limited to those physician-owned hospitals that do not have physician owners who refer patients to the hospital.

The intent of the disclosures is to increase the transparency of the hospital's ownership and operations to patients as they make decisions about receiving care at the hospital.  
*Frequency:* Reporting—Occasionally;  
*Affected Public:* Business or other for-profit;  
*Number of Respondents:* 2,697;  
*Total Annual Responses:* 49,735,828;  
*Total Annual Hours:* 840,318.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on September 8, 2008.

OMB Human Resources and Housing Branch, Attention: OMB Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: July 31, 2008.

**Michelle Shortt,**

*Director, Regulations Development Group,  
Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0429]

#### **Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing on the use of advisory labeling of allergens in foods. FDA is developing a long-term strategy to assist manufacturers in using allergen advisory labeling that is truthful and not misleading, conveys a clear and uniform message, and adequately informs food-allergic consumers and their caregivers. To that end, FDA is soliciting comments and information to assist the agency in determining how manufacturers currently use advisory labeling, how consumers interpret different advisory labeling statements, and what wording is likely to be most effective in communicating to consumers the likelihood that an allergen may be present in a food. The agency is also interested in receiving comments about whether consumers find advisory labeling helpful for making food purchasing decisions. This public hearing is the first step in closing existing knowledge gaps in developing our long-term strategy.

**DATES:** The public hearing will be held on September 16, 2008, from 9 a.m. to 4:30 p.m. The closing date for registration is September 8, 2008. See

section V of this document for other dates associated with participation in the hearing. Submit written or electronic comments (i.e., submissions other than notices of participation and written material associated with an oral presentation) by January 14, 2009. The administrative record of the hearing will remain open until January 14, 2009.

**ADDRESSES:** *Public hearing.* The public hearing will be held at the Harvey W. Wiley Federal Building, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, (Metro stop: College Park on the Green Line).

*Registration.* Submit electronic notices of participation for the hearing to <http://www.cfsan.fda.gov/register.html>. We encourage you to use this method of registration, if possible. Submit written notices of participation by mail, fax, or e-mail to Isabelle Howes, U.S. Department of Agriculture Graduate School, 600 Maryland Ave., SW., suite 330, Washington, DC 20024-2520, FAX: 202-479-6801, or e-mail: [Isabelle\\_Howes@grad.usda.gov](mailto:Isabelle_Howes@grad.usda.gov). You may also submit oral notices of participation by phone to Isabelle Howes, U.S. Department of Agriculture Graduate School (see **FOR FURTHER INFORMATION CONTACT**).

*Written material associated with an oral presentation.* Submit written material associated with an oral presentation by mail, fax, or e-mail to Isabelle Howes.

*Comments.* Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. For additional information on submitting comments, see section VI in this document.

**FOR FURTHER INFORMATION CONTACT:**

*For questions about registration or written material associated with an oral presentation, or to register orally:* Isabelle Howes, 202-314-4713.

*For all other questions about the hearing or if you need parking or special accommodations due to a disability:* Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301-436-1731, e-mail: [Juanita.Yates@fda.hhs.gov](mailto:Juanita.Yates@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Food allergies affect approximately two percent of adults and about five

percent of infants and young children in the United States. Currently, there is no cure for food allergies. The only successful method to manage food allergies is avoidance of foods containing allergens. Consumers can attempt to avoid food substances to which they are allergic by reading ingredient labels to see whether a food product contains an allergenic ingredient. However, allergenic substances may be inadvertently incorporated into food products that are not formulated to contain these substances; consequently, their presence is not required to be declared on food labels. FDA is concerned with food allergens, including food allergens inadvertently incorporated into manufactured foods, due to the number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in a food. This concern has prompted several agency actions targeting food manufacturers, including: (1) Issuing a notice to manufacturers entitled "Label Declaration of Allergenic Substances in Foods" in 1996 (Ref. 1); (2) forming an FDA/state partnership in 1998 to increase industry's understanding of food allergens and to identify effective manufacturing controls; and (3) issuing a food allergen guidance document in 2001 (Ref. 2). Information on these initiatives is available at the FDA Web site on allergens at <http://www.cfsan.fda.gov/~dms/wh-alrgy.html>.

FDA stated in the 1996 notice to manufacturers that it is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (*allergen*)."<sup>1</sup> FDA advised that, because adhering to current good manufacturing practices (CGMPs) is essential for effective reduction of adverse allergic reactions, advisory labeling<sup>1</sup> should not be used in lieu of adherence to CGMPs. The agency urged food manufacturers to take all steps necessary to eliminate cross-contact<sup>2</sup>

<sup>1</sup> The purpose of advisory labeling is generally to alert food-allergic consumers to the possibility of allergen cross-contact. Although these labels vary by content, common formulations include "This product was processed on machinery used to process (*allergen*)" and "May contain (*allergen*)."<sup>1</sup> While this document uses, where appropriate, the term "advisory labeling," FDA considers the term "advisory labeling" to be synonymous with "precautionary labeling," a term sometimes used to describe these circumstances.

<sup>2</sup> Cross-contact occurs when a residue or other trace amount of a food allergen is present on a food contact surface or production machinery, or is airborne, and unintentionally becomes incorporated into a product not intended to contain the allergen. Cross-contact may also result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or

and to ensure the absence of allergens in their finished food products. In addition, FDA encouraged manufacturers to declare voluntarily any allergenic ingredient of a flavor, spice, or color by identifying the allergenic ingredient in the ingredient list.

#### *A. Food Allergen Labeling and Consumer Protection Act of 2004*

On August 2, 2004, the United States Congress enacted the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of Public Law No. 108–282). FALCPA amended the Federal Food, Drug, and Cosmetic Act (the act) by imposing new labeling requirements on packaged foods that contain "major food allergens." Section 201(qq) of the act (21 U.S.C. 321(qq)) defines "major food allergen" as milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans or any other ingredient that contains protein derived from one of these foods or food groups. FALCPA requires that the labels of foods that contain an ingredient that is a major food allergen declare this ingredient in one of two ways: (1) By including the name of the food source from which the allergen is derived in parentheses following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major food allergen does not appear elsewhere in the ingredient statement or is not used in the common or usual name of the ingredient, or (2) by placing the word "Contains" followed by the name of the food source from which the major food allergen is derived immediately after or adjacent to the list of ingredients.

These allergen labeling requirements assist consumers in avoiding substances to which they are allergic. However, as previously discussed in this section, allergenic substances may be inadvertently incorporated into food products that are not formulated to contain them. FALCPA does not require the use of advisory labeling, including statements describing the potential presence of unintentional ingredients in food products resulting from the food manufacturing process.

#### *B. Information Available to FDA Regarding Advisory Labeling*

FDA has gathered information on advisory labeling by conducting its own consumer research and reviewing other published consumer research.

production equipment. FDA considers the term "cross-contact" to be synonymous with "cross-contamination," a term sometimes used to describe these circumstances.

Additionally, the agency investigated cross-contact that occurs during manufacturing and examined manufacturers' use of advisory labeling to alert consumers to the possibility that a food may contain allergens. The information FDA has collected provides insight into the types of advisory statements currently used by manufacturers and the reasons manufacturers use advisory labeling. Furthermore, the consumer research provides an understanding as to how consumers perceive particular advisory statements and what wording consumers prefer and find credible. FDA's findings are summarized as follows:

#### 1. Cross-Contact and Use of Advisory Labeling

FDA has found that unintentional cross-contact of foods with major food allergens may occur at almost any step of the manufacturing process and for various reasons (Ref. 3). Cross-contact can occur due to allergens in raw ingredients or in processing aids, allergens in reworked product,<sup>3</sup> and allergen carry-over from the use of shared equipment. Such potential sources of unintentional allergen cross-contact exist regardless of the manufacturer's size or food product. Many food manufacturers have allergen-control measures in place, such as the use of dedicated facilities or dedicated production lines, to prevent the cross-contact of major food allergens with their products. Manufacturers also use a variety of advisory statements on package labels, such as, "May contain (*allergen*)," "Produced in a plant that processes (*allergen*)," "Produced on shared equipment that processes (*allergen*)," and "Processed on equipment that also processes (*allergen*)."<sup>3</sup> These manufacturers use advisory labeling for a variety of reasons, such as to advise consumers of the potential presence of an allergen, to avoid the need to develop and use multiple labels, or to reduce legal liabilities.

#### 2. Consumer Studies

FDA surveyed food-allergic adults or their caregivers and non-food-allergic adults to learn which of the following food-allergen advisory statements they preferred (Ref. 4):

<sup>3</sup> As a verb, "rework" refers to the practice of reintroducing food product material that has been through some or all of the manufacturing process into an earlier stage of the production process of a subsequently produced food product. As a noun or adjective, "rework" refers to the food product material that is reintroduced into the production process.

(1) "Allergy Information: May contain peanuts."

(2) "May Contain Peanuts."

(3) "Manufactured on the same equipment as foods that contain peanut."

(4) "Produced in a facility with an allergy control plan. The possibility of contact with allergenic ingredients has been minimized. May still contain trace amount of peanut."

Survey participants preferred the statement "Allergy Information: May contain peanuts" over the other three statements. This finding is similar to other research that shows that people prefer warning information that is preceded by signal words, such as "Allergy Information," possibly because signal words help to quickly draw people's attention to important information (Ref. 5).

FDA also conducted an experiment that compared the four statements listed previously relative to buying, eating, or serving a food item (Ref. 4). The experiment yielded two important findings. The first important finding was that participants thought the risk of the food containing allergens was greater when any of the four advisory statements was on the food label than when there was no allergen advisory statement. The second important finding was that participants answered the questions about buying, eating, or serving the product differently depending on which advisory statement they were responding to. The experimental results showed that participants who looked at food packages bearing the advisory statements "Allergy information: May contain peanuts" or "May contain peanuts" believed these foods were more likely to contain peanuts. In contrast, participants looking at food packages with the other two statements believed those foods were less likely to contain peanuts.<sup>4</sup>

FDA also reviewed research conducted by the Food Allergy & Anaphylaxis Network (FAAN). FAAN's consumer surveys explored how consumers with food allergies responded to advisory labeling by either heeding it or ignoring it (Ref. 6). According to FAAN's consumer surveys, consumers with food allergies are increasingly ignoring advisory

labeling. Additional FAAN research examined retail packaged foods bearing various advisory labeling statements for peanuts and then analyzed the products to determine the prevalence of peanut residue. FAAN's analysis found detectable peanut residues in some of the products with allergy advisory statements. This finding is important because it indicates that allergic consumers who ignore advisory labeling statements are risking their health by consuming foods that have advisory labeling because some of these foods contain allergens.

#### *C. Other Initiatives on Food Allergen Advisory Labeling*

The use of advisory labeling has steadily increased in the United States. As mentioned in section I.B.1. of this document, different food companies use different advisory statements and have different reasons for using advisory labeling. FDA is aware that voluntary criteria for determining when to use advisory labeling exist in the United States. In 2001, in response to food allergy concerns, the Food Allergy Issues Alliance (Ref. 7), a private group of representatives from industry, a trade group, a consumer group, and academia recommended using the following criteria to evaluate a food to determine whether advisory labeling is appropriate:

- Whether the presence of a major food allergen is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product, or other means;
- Whether the risk of presence of a major food allergen is unavoidable even when current good manufacturing practices are followed;
- Whether a major food allergen is present in some, but not all, of the product; and
- Whether the presence of a major food allergen is potentially hazardous.

FDA is aware that other countries have developed or are currently developing criteria to ensure uniformity in the use of advisory labeling to warn consumers that a food may inadvertently contain an allergen. The Canadian government is currently reviewing precautionary statements for food allergens and making recommendations regarding their use on the labels of packaged foods. For example, Canada is updating its policy to restrict the options for different precautionary statements. The proposed options for precautionary statements in Canada are: (1) "may contain (allergen)" or (2) "not suitable for consumption by persons with an allergy to (allergen)" (Ref. 8). Further, where incoming

ingredients have been labeled with a precautionary statement, manufacturers are advised to use the same statement on the finished product label unless the allergen in the finished product is not likely to represent a health risk.

Similar initiatives are evolving in Australia and New Zealand. An industry forum has developed the Voluntary Incidental Trace Allergen Labeling (VITAL) procedure to provide a risk-based approach for food manufacturers to use in assessing the impact of allergen cross-contact and to provide appropriate allergen advisory labeling (Ref. 9). The VITAL Allergen Action Level Grid ("Vital Grid") determines whether allergens present in a food due to incidental cross-contact should be labeled and, if so, whether this labeling should state whether an allergen may be present or whether an allergen is actually present (i.e., identified as an ingredient). VITAL uses a three-level grid to determine if the presence of residual protein from allergenic substances through unavoidable cross-contact warrants advisory labeling. The VITAL Action Levels are: (1) Action Level 1—Green Zone—advisory labeling is not required for the allergen under evaluation; (2) Action Level 2—Yellow Zone—advisory labeling stating that the allergen under evaluation may be present is advised; and (3) Action Level 3—Red Zone—significant levels of the allergen are likely to be present in the food; therefore, listing the allergen in the ingredient list is advised.

#### *D. Need for Long-Term United States Strategy to Manage Allergen Advisory Labeling*

As previously discussed in this document, FDA has reviewed available information and data and found that the use of advisory label statements is not uniform. In addition, research indicated a range of consumer understanding and behavior with regard to advisory labeling. Research also indicated that some food products that contain advisory labeling have been shown to contain detectable residues of food allergens (Ref. 6). Allergic consumers who ignore advisory label statements assume the risk of potential adverse reactions by consuming these food products. If manufacturers choose to use advisory labeling to inform consumers of the potential presence of food allergens in the finished products, such labeling must be truthful and not misleading and should provide clear, uniform, and accurate information to food-allergic consumers about the potential presence of food allergens. As currently used in the marketplace,

<sup>4</sup> It is important to keep in mind that these two consumer research studies focused on the presence of peanuts. Peanut allergy can produce severe allergic responses, and even those not affected by peanut allergy appear to be aware that peanut allergy is serious for those with the allergy. The research results may have been different had a food allergen other than peanut been the subject of the advisory statements.

advisory labeling may not be protecting the health of allergic consumers; therefore, FDA believes that it is in the best interest of the public health, especially for food-allergic consumers, that FDA develop a long-term strategy to address allergen advisory labeling.

## II. Purpose and Scope of the Hearings

FDA is developing a long-term strategy to assist manufacturers in using allergen advisory labeling that is truthful and not misleading, conveys a clear and uniform message, and adequately informs allergic consumers and their caregivers. To that end, FDA is soliciting comments and information to assist the agency in determining how manufacturers currently use advisory labeling, how consumers interpret different advisory labeling statements, and what wording is most effective in communicating to consumers the likelihood that an allergen may be present in a food. The agency is also interested in learning whether consumers find advisory labeling helpful for making food purchasing decisions.

The scope of this hearing is determined by this document. FDA invites general comments on the issues and questions listed in section III of this document.

## III. Issues and Questions for Discussion

The following issues and questions will be discussed at the public hearing:

*Issue 1:* FDA is developing a long-term strategy to assist manufacturers in ensuring that allergen advisory labeling is truthful and not misleading, conveys a clear and uniform message, and adequately informs allergic consumers and their caregivers. To help us better understand under what circumstances manufacturers use advisory labeling, we ask the following questions:

Question 1. What manufacturing circumstances prompt manufacturers to place advisory statements on a food label? What manufacturing circumstances do not prompt manufacturers to include an advisory statement? Why?

Question 2. If we decide to develop guidance for using advisory labeling, should we incorporate any of the guidelines from the Food Allergy Issues Alliance or the principles of the VITAL system? If so, why?

Question 3. Are there circumstances under which there is no possibility of cross-contact with a food allergen? If so, what are they?

Question 4. When manufacturers declare an allergenic ingredient in the ingredient list or in the "Contains" statement, do they also use an advisory

statement indicating the presence of that ingredient? If so, why? What do allergic consumers think of such labeling? Do consumers consume the food product if they are allergic to the allergen referred to in the advisory statement? Is the presence of both an advisory statement and a "Contains" statement that include the same allergen on the same food label confusing? Why or why not?

Question 5. What criteria and considerations does a small firm rely on when determining whether to use advisory labeling? Are these the same criteria and considerations that a large firm relies on? How frequently does a small firm use advisory labeling compared to a large firm? If we decide to develop guidance for using advisory labeling, what options should we investigate to consider the circumstances of small firms?

Question 6. How do manufacturers decide whether to label their finished products with advisory labeling when their incoming ingredients are labeled with advisory statements?

*Issue 2:* FDA is also assessing whether advisory labeling is useful to consumers and how consumers interpret advisory labeling statements. Currently, industry uses many different advisory statements, such as "May contain (allergen)," "(allergen) traces," "Produced on shared equipment that processes (allergen)," and "Produced in a plant that processes (allergen)." We are concerned that allergic consumers may be risking their health by ignoring labeling designed to inform them of the potential presence of allergens in foods. To help us better understand what type of advisory labeling is most effective in helping consumers avoid adverse allergic reactions, we ask the following questions:

Question 7. Consumer research suggests that different advisory statements convey different degrees of potential for the inadvertent presence of an allergen in a food. What message do manufacturers want to convey by an advisory statement generally?

Question 8. What specific advisory statements adequately inform consumers of the potential risk of cross-contact with allergenic materials? What advisory statements most accurately communicate to consumers and their caregivers the potential risk of the presence of the allergen? Why?

Question 9. If you are a food-allergic consumer or caregiver to such a consumer, do you ever ignore advisory statements? If so, which types of statements, and why?

Question 10. In addition to the information and data mentioned in this document, what additional information

or data are available that would assist us in understanding consumers' perceptions of, use of, and need for specific advisory statements and advisory labeling in general?

*Issue 3:* FDA is assessing how advisory statements should be worded to be the most effective in communicating the likelihood that an allergen may be present in a food. Consumer focus group research shows that the elements essential for an effective warning or safe handling statement are: a description of the hazard, handling instructions for avoiding the hazard, and an instructional statement that describes conditions under which the hazard occurs and what action to take if the hazard is not avoided (Ref. 10). This same research indicates that label messages are more credible when consumers know the reason for the message. The agency has previously used this consumer study information to craft the warning statements and safe handling statements found in 21 CFR 101.17. To help us better understand how advisory statements should be worded to be the most effective in communicating the likelihood that an allergen may be present in a food, we ask the following questions:

Question 11. What elements are needed in an advisory statement to adequately inform consumers of the potential for the inadvertent presence of an allergen and would communicate to allergic consumers a consistent and effective message regarding the risk of consuming the product?

Question 12. How would the use of consistent and effective advisory labeling affect consumer understanding of the potential for an allergen to be present in a food?

## IV. Notice of Hearing Under 21 CFR Part 15

Under authority delegated by the Commissioner of Food and Drugs (the Commissioner), the Associate Commissioner for Policy and Planning finds that it is in the public interest to permit persons to present information and views at a public hearing regarding the use of allergen advisory labeling and is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or his designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the hearing (either by making a presentation or as a member of the audience) must file a notice of participation (see **DATES, ADDRESSES, FOR FURTHER INFORMATION**

**CONTACT**, and section V of this document). Under authority delegated by the Commissioner, the Associate Commissioner for Policy and Planning has determined under § 15.20(c) that advance submissions of oral presentations are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e), and that the submission of a comprehensive outline or summary is an acceptable alternative to the submission of the full text of the oral presentation. For efficiency, we request that individuals and organizations with common interests consolidate their requests for oral presentation and request time for a joint presentation through a single representative. After reviewing the notices of participation and accompanying information, we will schedule each oral presentation and notify each participant of the time allotted to the presenter and the approximate time that the presentation is scheduled to begin. If time permits, we may allow interested persons who attend the hearing but did not submit a notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing.

After the hearing, the schedule and a list of participants will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading of this document.

To ensure timely handling of any mailed notices of participation, written material associated with presentations, or comments, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this document along with the statement "Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments."

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to the procedures and limitations in § 10.206, to videotape, film, or otherwise record FDA's public

administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). For additional information about transcripts, see section VII in this document.

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the appropriate contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of these provisions as specified in §§ 10.19 and 15.30(h). In particular, § 15.21(a) states that the notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time. If the public interest requires, e.g., if a hearing is to be conducted within a short period of time, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given. If the public interest requires, the notice may also provide for submitting notices of participation at the time of the hearing. In this document, the conditions for the hearing specify that notices of participation be submitted electronically to an agency Web site, to a contact person who will accept notices of participation by mail, telephone, fax, or e-mail, or in person on the day of the hearing (as time and space permits). In addition, the conditions for the hearing specify that written material associated with an oral presentation be provided to a contact person who will accept it by mail, fax, or e-mail rather than to the Division of Dockets Management. We are using these procedures to facilitate the exchange of information between participants and the agency. Under authority delegated by the Commissioner, the Associate Commissioner for Policy and Planning finds under § 10.19 that no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law if notices of participation are submitted by any of the procedures listed in this document.

#### **V. How to Participate in the Hearing**

Registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis. The closing date for registration is September 8, 2008. The notice of participation may be submitted electronically, orally, or by fax, mail, or e-mail (see **ADDRESSES** and **FOR FURTHER**

**INFORMATION CONTACT**). We encourage you to submit your notice of participation electronically. A single copy of any notice of participation is sufficient.

The notice of participation must include your name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available). If you wish to request an opportunity to make an oral presentation during the open public comment period of the hearing, your notice of participation also must include the title of your presentation, the sponsor of the oral presentation (e.g., the organization paying travel expenses or fees), if any; and the approximate amount of time requested for the presentation. Presentations will be limited to the questions and subject matter identified in section III of this document, and, depending on the number of requests received, we may be obliged to limit the time allotted for each presentation (e.g., 5 minutes each).

Under § 15.20(c), if you request an opportunity to make an oral presentation, you must submit your presentation (either as the full text of the presentation or as a comprehensive outline or summary). You may submit your presentation by e-mail, fax, or mail. A single copy of your presentation is sufficient. See **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** for information on where to send your presentation.

Persons who wish to request an opportunity to make an oral presentation must submit a notice of participation by August 26, 2008, and also must submit either the full text of the oral presentation or a comprehensive outline or summary of the oral presentation by September 8, 2008. Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. All other persons wishing to attend the hearing must submit a notice of participation by September 8, 2008. Persons requiring special accommodations due to a disability must submit a notice of participation by September 8, 2008, and should inform the contact person of their request (see **FOR FURTHER INFORMATION CONTACT**). Persons wishing to park onsite should inform the contact person of their request by September 10, 2008.

We will also accept notices of participation onsite on a first-come, first-served basis; however, space is limited and registration will be closed when the maximum seating capacity is

reached. Requests for an opportunity to make a presentation from individuals or organizations that did not make such a request in advance may be granted if time permits.

Persons who submit a notice of participation in advance of the hearing should check in at the on-site registration desk between 8 a.m. and 9 a.m. Persons who wish to submit a notice of participation on-site on the day of the hearing may do so at the registration desk between 8 a.m. and 9 a.m. We encourage all participants to attend the entire hearing. Because the hearing will be held in a Federal building, hearing participants must present photo identification and plan adequate time to pass through the security system.

We may post all submissions and received comments without change to <http://www.regulations.gov>, including any personal information provided.

#### VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments for consideration at or after the hearing in addition to, or in place of, a request for an opportunity to make an oral presentation (see section V of this document). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

#### VII. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office

of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

#### VIII. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**) and interested parties may see them between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, "Notice to Manufacturers, Label Declaration of Allergenic Substances in Foods," June 10, 1996.
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3. Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, "Report to the Committee on Health, Education, Labor, and Pensions, United States Senate and the Committee on Energy and Commerce, United States House of Representatives," July 2006, accessible at <http://www.cfsan.fda.gov/~acrobot/alrgrep.pdf>
4. Verrill, Linda and Conrad J. Choinière. (2009). "Are Food Allergen Advisory Statements Really Warnings?: Variation in Consumer Preferences and Consumption Decisions," *Journal of Food Products Marketing*, 15(2) (accepted for publication).
5. Wogalter, M.S., M.J. Kalsher, R. Rashid, (1999), "Effect of Signal Word and Source Attribution on Judgments of Warning Credibility and Compliance Likelihood," *International Journal of Industrial Ergonomics*, 1999 24:185-192.
6. Hefle, S.L., T.J. Furlong, L. Niemann, H. Lemon-Mule, S. Sicherer, S.L. Taylor, (2007), "Consumer Attitudes and Risks Associated With Packaged Foods Having Advisory Labeling Regarding the Presence of Peanuts," *Journal of Allergy and Clinical Immunology*, 120(1):171-176.
7. Food Allergy Issues Alliance, "Food Allergen Labeling Guidelines," May 2001.
8. Canadian Food Inspection Agency, "Precautionary Labelling Regarding Food Allergens in Pre-packaged Foods" September 25, 2007, accessible at <http://www.inspection.gc.ca/english/fssa/invenq/inform/20070925e.shtml> on March 26, 2008.
9. Australian Food and Grocery Council Allergen Forum, "Food Industry Guide to Allergen Management and Labelling," 2007 revised edition, accessible at [http://www.allergenbureau.net/downloads/allergen-guide/Allergen\\_Guide\\_2007.pdf](http://www.allergenbureau.net/downloads/allergen-guide/Allergen_Guide_2007.pdf) on March 26, 2008.
10. Levy, A.S., "Review of Research Communicating Warning Information," Consumer Studies Branch, Office of Scientific Analysis and Support, Center for Food Safety and Applied Nutrition, Food and Drug Administration, June 1997.

Dated: July 30, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Initial Review Group, Subcommittee I—Career Development.

*Date:* September 30–October 1, 2008.

*Time:* 8 a.m. to 5 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza National Airport, 1480 Crystal Drive, Arlington, VA 22202.

*Contact Person:* Sonya Roberson, PhD, Scientific Review Officer, Resources And Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8109, Bethesda, MD 20892, 301-594-1182, [roberson@mail.nih.gov](mailto:roberson@mail.nih.gov).

*Name of Committee:* National Cancer Institute Initial Review Group, Subcommittee H—Clinical Groups.

*Date:* October 13–14, 2008.

*Time:* 8 a.m. to 9 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Timothy C. Meeker, MD, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8103, Bethesda, MD 20892, (301) 594-1279, [meekert@mail.nih.gov](mailto:meekert@mail.nih.gov).