scheduled between approximately 11:15 a.m. and 11:45 p.m. and between approximately 3:30 p.m. and 4 p.m. on August 16, 2007. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 31, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 1, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 16, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–14088 Filed 7–19–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD, 301–977–8900.

Contact Person: Mimi Phan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Mimi.Phan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533 or 3014512535. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss updated information on the risks and benefits of erythropoeisis-stimulating agents (ARANESP, Amgen, Inc., EPOGEN, Amgen, Inc., and PROCRIT, Amgen, Inc.) when used in the treatment of anemia due to chronic renal failure. This discussion follows a March 9, 2007, FDA Public Health Advisory regarding the use of these agents (*http://www.fda.gov/cder/drug/advisory/RHE2007.htm*).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 27, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 17, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 20, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Mimi Phan at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 16, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–14086 Filed 7–19–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0277]

Food Labeling: Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria; 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 concerning the use of symbols to communicate nutrition

information on food labels. The purpose of the hearing is for FDA to solicit information and comments from interested persons about programs currently in use regarding the use of symbols to communicate nutrition information on food labels.

DATES: The public hearing will be held on September 10 and 11, 2007, from 9 a.m. to 5 p.m. See section V of this document for additional dates associated with registration and 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 November 12, 2007. The administrative record of the hearing will remain open until November 12, 2007.

ADDRESSES: *Public hearing.* The public hearing will be held at The Inn & Conference Center by Marriott, University of Maryland, University College, 3501 University Blvd. E., Adelphi, Maryland 20783.

Registration and notice of participation and written material associated with an oral presentation. Submit electronic requests to register and notices of participation for the hearing to *http://www.cfsan.fda.gov/register.html*. We encourage you to use this method to submit notices of participation, if possible. Submit written requests to register and notices of participation, and written material associated with an oral presentation to: Kathy Houston, Z-Tech Corp., 1803 Research Blvd., suite 301, Rockville, MD 20850, 301–251–4976, FAX: 301–315–2801, or e-mail: *khouston@z-techcorp.com*.

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.fda.gov/dockets/ecomments*. For additional information on submitting comments, see section VI in this document.

FOR FURTHER INFORMATION CONTACT: *To submit an oral or written notice of participation by phone, by fax, or by e-mail, or to submit written material associated with an oral presentation by fax or by e-mail*: Kathy Houston, Z-Tech Corp., 1803 Research Blvd., suite 301, Rockville, MD 20850.

For all other questions about the hearing or if you need 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*.

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535) amended the Federal Food, Drug, and Cosmetic Act (the act) to require nutrition labeling on the labels of packaged foods to enable consumers to make more informed and healthier food choices in the context of their daily diet. In 1993, FDA established regulations that implemented the 1990 amendments, including provisions concerning the use of claims on the label or in labeling of a food. Among these regulations, the agency set forth general principles for nutrient content claims (21 CFR 101.13), which are claims that characterize the level of a nutrient in a food (e.g., ''low fat,'' ''good source of fiber''), and for health claims (21 CFR 101.14), which are claims that characterize the relationship of a food substance to a disease or health-related condition (e.g., ''calcium may reduce the risk of osteoporosis'').

A. Use of Nutrition Symbols on Food Labels in the United States.

In recent years, domestic manufacturers and retailers have begun to include symbols that indicate nutritional quality on the label or in labeling of a food. Symbol programs have been instituted by companies to promote their products and provide consumers with easily understandable nutrition information to aid them in their food purchases. Various food manufacturers, grocery stores, trade organizations, and health organizations have developed, or are currently developing, symbols and icons that indicate specific nutritional attributes of food products. Although each symbol intends to indicate that the food product bearing the symbol is a healthful choice, each symbol program has different nutrient requirements. The selected nutrients and the nutrient levels required for eligibility vary among the different symbol programs in use. With the increasingly widespread availability of these symbols from manufacturers, retailers, and third party organizations, it is possible that eligible food products could bear multiple nutrition symbols.

B. Use of Nutrition Symbols on Food Labels in Other Countries

A few countries around the world have already instituted voluntary labeling systems for government-designed front-label[1] nutrition symbols. These symbol systems vary in their format. Some systems have detailed graphic illustrations that indicate the content of a number of selected nutrients, while others simply present a single icon indicating that a food is healthful (with further information available elsewhere, such as in booklets and web sites). Also in use internationally are industry-designed nutrition symbol systems that are available for use in countries that do not have a government-designed symbol program or, in certain countries, that exist as alternatives to the government-designed symbols.

II. Purpose and Scope of the Hearing

The purpose of the hearing is for FDA to solicit information and comments from interested persons about programs currently in use regarding the use of symbols to communicate nutrition information on food labels.

This notice describes the scope of the hearing. We invite information and comment on the issues and questions in section III of this document. If you are interested in this hearing or this subject, you may address as many of the following questions as you wish. We do not expect you to address all questions. When possible, please provide scientific information and data in support of your comments. In addition, to the extent possible, please provide as specific information as is feasible about the estimated costs and benefits associated with your responses (e.g., the costs and benefits of current practices and/or the cost and benefits of any recommendations you may make).

III. Issues and Questions for Discussion

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

Issue 1: There are many food label nutrition symbol programs currently in the domestic and international marketplace. Each system uses different nutrition criteria and requirements regarding eligibility for use. The agency would like information on the food products that bear nutrition symbols and the nutrient requirements for those symbols.

Question 1. In what product categories are nutrition symbols used (e.g., packaged foods, fresh produce, meat/poultry, seafood)?

Question 2. Which symbols are nutrient specific, and which are summary symbols based on multiple nutrients?

[1] As used in this notice, the term ''front label'' means the part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. In the United States, the front label is known as the principal display panel (21 CFR 1.1).

Question 3. What are the nutritional criteria, including calories, included in a symbol system and how were those particular nutritional criteria chosen for inclusion?

Question 4. What nutrient thresholds and/or algorithms are used to determine if a food product may display a nutrient specific or summary symbol?

Question 5. Are nutrition symbols presented together with front label nutrition claims such as ''low fat'' or ''good source of calcium'' and, if so, to what extent and for what types of claims?

Question 6. Are there programs to educate consumers to understand the nutrition symbols or is all information contained in the symbols? When education programs are available, how are they presented?

Issue 2: The presence of nutrition symbols could affect the food purchasing decisions of consumers. Symbols could help consumers make food choices, but it is also possible that symbols could introduce confusion when making decisions. The agency would like information on consumer research that supported the development of these programs and research that illustrates how these programs are understood and utilized by consumers.

Question 7. What are consumer attitudes toward nutrition symbols?

Question 8. What are consumer attitudes toward products or brands that carry a nutrition symbol compared to other products or brands in the same product category (e.g., cereals) and in other categories that do not carry such a symbol?

Question 9. What are consumer interpretations of symbol-carrying products or brands in terms of their overall healthfulness, specific health benefits, featured nutrition attributes, nonfeatured nutrition attributes, quality, safety, and any other non-nutrition attributes?

Question 10. What is consumer perception of the presence of multiple and different nutrition symbols on front labels of different brands in a given product category, e.g., cereals?

Question 11. What is consumer interpretation of the co-existence on the food label of symbols and/or other nutrition messages, when present, and quantitative nutrition information (e.g., the Nutrition Facts label that appears on foods in the United States)?

Question 12. What is consumer interpretation of the co-existence of front-label nutrition symbols and nutrition symbols present on the tags of supermarket shelves, when available?

Question 13. When do consumers use nutrition symbols and what do they use them for?

Question 14. Do nutrition symbols on food labels direct consumers toward purchase of foods that bear them and, if so, to what extent?

Question 15. Do symbols affect the nutritional quality of the total diet of consumers who use the symbols and, if so, to what extent?

Issue 3: The availability of a nutrition symbol for use on the food label could have an impact on costs for both industry and for consumers. The agency would like information on possible economic impacts.

Question 16. To what extent, if any, have products been developed or re-formulated to qualify them for a given nutrition symbol?

Question 17. What are the costs associated with product development, re-formulation, or both?

Question 18. What are the costs associated with putting symbols on packages?

Question 19. What, if any, are the price differences between symbol-carrying products and other products within the same category?

Question 20. Has inclusion of nutrition symbols on the labels of food products affected the sales of those products?

IV. Notice of Hearing Under 21 CFR Part 15

By delegation from the Commissioner of Food and Drugs (the Commissioner) (Staff Manual Guide 1410.21 paragraph 1.f. (5)), the Assistant Commissioner for Policy finds that it is in the public interest to permit persons to present information and views at a public hearing regarding the use of symbols to communicate nutrition information on food labels 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). By delegation from the Commissioner (Staff Manual Guide 1410.21 paragraph 1.f. (5)), the Assistant Commissioner for Policy 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 notice.

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 notice along with the statement ''Food Labeling: Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria; Public Hearing.''

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 notice 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 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. By delegation from the Commissioner (Staff Manual Guide 1410.21 paragraph 1.f. (5)), the Assistant Commissioner for Policy 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 the procedures listed in this notice rather than to the Division of Dockets Management.

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 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 at the hearing must submit a notice of participation by August 24, 2007, and also must submit either the full text of the oral presentation, or a comprehensive outline or summary of the oral presentation, by August 31, 2007. All other persons wishing to attend the hearing must submit a notice of participation by August 31, 2007. Persons requiring special accommodations due to a disability must submit a notice of participation by August 31, 2007, and should inform the contact person of their request (see **FOR FURTHER INFORMATION CONTACT**). Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing.

We also will accept notices of participation onsite on a first come, first served basis; however, the anticipated maximum seating capacity is 75 to 100, 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 8:30 and 9 a.m. Persons who wish to submit a notice of participation onsite may do so at the registration desk between 8:30 and 9 a.m. on either day of the hearing. We encourage all participants to attend the entire hearing.

All submissions and comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, 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 two paper copies of any written comments, except that individuals may submit one copy. Comments are to be identified with the agency name and 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.

VII. Transcripts

Transcripts of the hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets*approximately 30 days after the hearing. You may place orders for copies of the transcript through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers lane, rm. 6–30, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: July 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–14046 Filed 7–19–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Defense . . . Be ALERT; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Atlanta District and Southeast Regional Office (SER), in collaboration with Georgia Food Safety and Defense Task Force, and the Metro Environmental Health Directors Food Service Advisory