



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 26 2000 0976 '00 OCT 31 A10:18

The Honorable John B. Breaux
United States Senate
Washington, D.C. 20510-1803

Dear Senator Breaux:

Thank you for your letter of September 27, 2000, on behalf of your constituent, Ms. Kathleen Fegan of New Orleans, Louisiana. Ms. Fegan is opposed to the use of the word "fresh" on labels of foods that have undergone any type of processing.

By way of background, the Food and Drug Administration (FDA) held a public meeting on July 21, 2000, to discuss the use of the term "fresh" in the labeling of foods processed with alternative nonthermal technologies. The purpose of the meeting was to determine whether the use of the term "fresh" is truthful and not misleading on foods processed with these alternative technologies and to determine what criteria FDA should use when considering the use of this term with future technologies. The transcript of this meeting is available on FDA's website at <http://vm.cfsan.fda.gov/~dms/1lfresh.html>.

In response to a request for additional time to comment on this matter, FDA has reopened the comment period until November 20, 2000. We have forwarded your correspondence to the docket for this matter for inclusion in the record. We wish to assure you that Ms. Fegan's comments will be given careful consideration.

We have enclosed a copy of the July 3, 2000, Federal Register notice that announced the meeting and explained what information FDA was seeking. We have also enclosed the September 20, 2000, Federal Register notice that announces the reopening of the comment period and explains how to submit comments. We hope this information is helpful.

00N-1351

ANS/1
EMC89

Page 2 - The Honorable John B. Breaux

Thanks again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

Jm

2 Enclosures

cc: Dockets Management Branch (HFA-305)
Docket No. 00N-1351

[Federal Register: July 3, 2000 (Volume 65, Number 128)]
[Proposed Rules]
[Page 41029-41031]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr03jy00-38]

=====

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00N-1351]

Food Labeling; Use of the Term "Fresh" for Foods Processed With
Alternative Nonthermal Technologies; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the use of the term "fresh" in the labeling of foods processed with alternative nonthermal technologies. The purpose of the meeting is to determine whether the use of the term "fresh" is truthful and not misleading on foods processed with these alternative technologies and to determine what type of criteria FDA should use when considering the use of the term with future technologies.

DATES: The public meeting will be held on July 21, 2000, from 8:30 a.m. to 4 p.m. Please preregister by July 14, 2000. Late registrations will be accepted contingent on space availability. Comments must be submitted no later than August 21, 2000.

ADDRESSES: The meeting will be held at the Holiday Inn City Centre, 300 East Ohio St., Chicago, IL, 312-787-6100.

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

FOR FURTHER INFORMATION CONTACT:

For registration: Kimberly Phillips or Darlene M. Bailey, Office of Public Affairs (HFR-CE645), Food and Drug Administration, 300 South Riverside Plaza, suite 550 South, Chicago, IL 60606, 312-353-7126 or FAX 312-886-3280.

[[Page 41030]]

For general information: Geraldine A. June, Center for Food Safety and Nutrition, Food and Drug Administration (HFS-822), 200 C St. SW., Washington, DC 20204, 202-205-4168 or FAX 202-205-5295.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 6, 1993 (58 FR 2302 at 2401), FDA published a final rule that established labeling regulations that govern the use of the terms ``fresh,`` ``freshly_____`` (e.g., ``freshly baked``) and ``fresh frozen`` as they appear on the labeling of foods, including the use of these terms in brand names and as sensory modifiers. As discussed in the final rule, we issued this regulation because of the continued misuse of the term ``fresh`` and related terms in the marketplace.

We concluded at that time that it was necessary to establish a definition for ``fresh`` to preclude the type of misuse that we encountered most often, i.e., use of the term to imply that a food is unprocessed, when in fact it has been processed. Thus, provisions in Sec. 101.95 (21 CFR 101.95) govern the use of the term ``fresh`` when used on the labels or in labeling of foods to suggest or imply that the food is unprocessed. Generally, the appearance of the term ``fresh`` on a label or in labeling means that the food in its raw state or finished form has not been frozen or subjected to any form of thermal processing or any other form of preservation. However, we provided that the following treatments do not preclude the food from bearing the term ``fresh``: (1) The addition of approved waxes or coatings, (2) the post-harvest use of approved pesticides, (3) the application of a mild chlorine wash or mild acid wash on produce, or (4) the treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray.

The regulation also notes that use of the term ``fresh`` is not precluded when it does not imply that the food is unprocessed, e.g., ``fresh`` may be used to describe pasteurized whole milk because consumers understand that almost all milk is pasteurized and, therefore, there is no misleading implication.

Recently, manufacturers have developed new alternative food processing technologies to control pathogens in foods while minimizing the thermal component of the process. Such processes include, but are not limited to, high pressure processing, pulsed electric field, pulsed light, submerged arc, and filtration.

FDA contracted with the Institute of Food Technologists (IFT) to review and evaluate the scientific information available on these new alternative technologies and to assist us in evaluating each technology's effectiveness in reducing and inactivating pathogens of public health concern. Where information on these technologies was too limited for a thorough evaluation and conclusion, IFT identified research needs. The final report of this work, entitled ``Kinetics of Microbial Inactivation for Alternative Food Processing Technologies`` (Ref. 1), is available on FDA's website at www.cfsan.fda.gov.

Manufacturers using these processes contend that their products maintain the same ``fresh`` characteristics as unprocessed products. Thus, these manufacturers have asked FDA if they may label these products with the term ``fresh.`` We are interested in obtaining the views of interested parties on the use of the term ``fresh`` for foods processed with these technologies. Thus, we have decided to hold a public meeting to engage interested parties in discussion on this issue. We will use information gathered at this meeting, as well as other information available to FDA, in considering whether to initiate rulemaking to amend Sec. 101.95.

In this notice, we are announcing a public meeting to discuss the use of the term ``fresh`` in the labeling of foods processed with the alternative technologies. We are soliciting public comment on whether the use of the term ``fresh`` is truthful and not misleading on foods processed with these alternative technologies and on what type of criteria FDA should use when considering the use of the term with future technologies. Specifically, we invite comment on the following questions:

1. Do consumers associate the term ``fresh`` with organoleptic

characteristics, nutritional characteristics, or some other characteristics?

2. Do consumers want a way to identify foods that taste and look fresh but have been processed to control pathogens?

3. What does industry think the term "fresh" means?

4. Is the term "fresh" when applied to foods processed with the new technologies misleading to consumers?

5. Do the new technologies preserve the foods?

6. Are the new technologies truly nonthermal?

7. Are there quantifiable parameters, e.g., level of nutrients, vitamins etc., that could be measured to determine if a food is "fresh"?

8. Is there a term other than "fresh" that can be used for foods processed with the new technologies?

9. Would consumers understand a new term?

10. What is the economic impact of allowing use of the term "fresh" for foods processed with the new technologies?

11. Would allowing the term "fresh" on foods processed with new technologies place small firms not able to use these technologies at an economic disadvantage?

At the public meeting, we will be addressing whether the use of alternative processing technologies should preclude the use of the term "fresh." Therefore, the public meeting will be restricted to the discussion of whether these processes fit the criteria for the use of the term "fresh" and not whether other aspects of the provisions in Sec. 101.95 should be reopened.

II. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, you must preregister in writing with the contact person for registration (address above) by July 14, 2000, by providing your name, title, business affiliation, address, telephone and fax number. Preregistered persons should check in before the meeting between 8 a.m. and 8:30 a.m. Persons who have not preregistered may register before the meeting between 8 a.m. and 8:30 a.m., dependent on space availability. To expedite processing, this registration information also may be sent to the contact person by FAX to 312-886-3280. 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 so inform the contact person 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 the persons who will give the presentation. Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

III. Comments

Interested persons may, on or before August 21, 2000, submit written comments to the Dockets Management Branch (address above). You may also

[[Page 41031]]

send comments to the Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or to the FDA website at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. Please address your comments to the docket number given at the beginning of this notice. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an

individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

IV. Transcripts

You may request a transcript of the meeting from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after August 11, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website at <http://www.fda.gov>.

V. Reference

We have placed the following reference on display in the Dockets Management Branch. You may see it at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Institute of Food Technologists, 'Kinetics of Microbial Inactivation for Alternative Food Processing Technologies,' A report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services, June 2, 2000.

Registration Form

Public Meeting on Use of the Term 'Fresh' on Foods Processed with Alternative Nonthermal Technologies

Instructions: To register, complete this form and mail it to the address of the contact person(s) for registration or fax it to 312-886-3280 by July 14, 2000.

Name, _____
 Title, _____
 Company, _____
 Address, _____
 Telephone, _____
 Fax, _____
 E-mail, _____

Please indicate the type of organization that 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 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, and depending on the number of people who register to make presentations, we will limit the time allotted for each presentation.

Dated: June 27, 2000.

Margaret M. Dotzel,
Associate Commissioner for Policy.
[FR Doc. 00-16716 Filed 6-28-00; 1:38 pm]
BILLING CODE 4160-01-F

"Dear Colleague" Letter on July 21, 2000 Public Meeting about Use of "Fresh" on Food Labels (June 28, 2000)

Home

much it would cost to excavate material from another site within the flood control storage zone, haul it to the project site and use as the fill material);

(iv) The cost of the project; and

(v) The nature and significance of any economic and/or natural resource benefits that would be realized as a result of the project.

(2) TVA may, in its discretion, decline to permit any project that would result in the loss of flood control storage.

(d) Recreational vehicles parked or placed within flood control storage zones of TVA reservoirs shall be deemed an obstruction affecting navigation, flood control, or public lands or reservations within the meaning of section 26a of the Act unless they:

(1) Remain truly mobile and ready for highway use. The unit must be on its wheels or a jacking system and be attached to its site by only quick disconnect type utilities;

(2) Have no permanently attached additions, connections, foundations, porches, or similar structures; and

(3) Have an electrical cutoff switch that is located above the flood control zone and fully accessible during flood events.

§ 1304.409 Variances.

The Vice President or the designee thereof is authorized, following consideration whether a proposed structure or other regulated activity would adversely impact navigation, flood control, public lands or reservations, power generation, the environment, or sensitive environmental resources, or would be incompatible with surrounding uses or inconsistent with an approved TVA reservoir land management plan, to approve a structure or activity that varies from the requirements of this part in minor aspects.

§ 1304.410 Indefinite or temporary moorage of recreational vessels.

(a) Recreational vessels' moorage at unpermitted locations along the shoreline of any TVA lake may not exceed 14 consecutive days at any one place or at any place within one mile thereof.

(b) Recreational vessels may not establish temporary moorage within the limits of primary or secondary navigation channels.

(c) Moorage lines of recreational vessels may not be placed in such a way as to block or hinder boating access to any part of the lake.

§ 1304.411 Navigation restrictions.

(a) Except for the placement of riprap along the shoreline, structures, land

based or water-use, shall not be located within the limits of safety harbors and landings establish for commercial navigation.

(b) Structures shall not be located in such a way as to block the visibility of navigation aids located on the shoreland or in the reservoir adjacent to the shoreline. Examples of navigation aids are lights, dayboards, and directional signs.

(c) Docks, piers, and boathouses located in coves, embayments, or creeks shall not extend more than one third the distance to the opposite shoreline at normal summer pool elevation.

(d) The establishment of "no-wake" zones outside approved harbor limits is prohibited at marinas or community dock facilities that are adjacent to or near a commercial navigation channel. In such circumstances, facility owners may, upon approval from TVA, install a floating breakwater along the harbor limit to reduce wave and wash action.

Appendix A To Part 1304—Section 26a of Tennessee Valley Authority Act of 1933, as Amended (49 Stat. 1079, 16 U.S.C. 831y-1)

Section 26a. The unified development and regulation of the Tennessee River system requires that no dam, appurtenant works, or other obstruction affecting navigation, flood control, or public lands or reservations shall be constructed, and thereafter operated or maintained across, along, or in the said river or any of its tributaries until plans for such construction, operation, and maintenance shall have been submitted to and approved by the Board; and the construction, commencement of construction, operation, or maintenance of such structures without such approval is hereby prohibited. When such plans shall have been approved, deviation therefrom either before or after completion of such structures is prohibited unless the modification of such plans has previously been submitted to and approved by the Board.

In the event the Board shall, within sixty (60) days after their formal submission to the Board, fail to approve any plans or modifications, as the case may be, for construction, operation, or maintenance of any such structures on the Little Tennessee River, the above requirements shall be deemed satisfied, if upon application to the Secretary of War, with due notice to the Corporation, and hearing thereon, such plans or modifications are approved by the said Secretary of War as reasonable adequate and effective for the unified development and regulation of the Tennessee River system.

Such construction, commencement of construction, operation, or maintenance of any structures or parts thereof in violation of the provisions of this section may be prevented, and the removal or discontinuation thereof required by the injunction or order of any district court exercising jurisdiction in any district in which such structures or parts thereof may be

situated, and the Corporation is hereby authorized to bring appropriate proceedings to this end.

The requirements of this section shall not be constructed to be a substitute for the requirements of any other law of the United States or of any State, now in effect or hereafter enacted, but shall be in addition thereto, so that any approval, license, permit, or other sanction now or hereafter required by the provisions of any such law for the construction, operation, or maintenance of any structures whatever, except such as may be constructed, operated, or maintained by the Corporation, shall be required, notwithstanding the provisions of this section.

[Note: The official text of section 26a of the Tennessee Valley Authority Act of 1933, as amended, is published at 16 U.S.C. 831y-1.]

Dated: September 5, 2000.

Kathryn J. Jackson,

Executive Vice President, River Systems Operations and Environment, Tennessee Valley Authority.

[FR Doc. 00-23424 Filed 9-19-00; 8:45 am]

BILLING CODE 8120-08-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00N-1351]

Food Labeling; Use of the Term "Fresh" for Foods Processed With Alternative Nonthermal Technologies

AGENCY: Food and Drug Administration, HHS.

ACTION: Reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to November 20, 2000, the comment period for a document published in the *Federal Register* of July 3, 2000 (65 FR 41029), that announced a public meeting to discuss use of the term "fresh" for foods processed with alternative technologies. FDA is taking this action in response to a request for more time to submit comments to FDA.

DATES: Submit written comments by November 20, 2000.

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

FOR FURTHER INFORMATION CONTACT:

Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4168 or FAX 202-205-5295.

SUPPLEMENTARY INFORMATION:**I. Reopening of Comment Period**

In the *Federal Register* of July 3, 2000 (65 FR 41029), FDA (we) published a document announcing a public meeting to discuss the use of the term "fresh" on foods processed with alternative nonthermal technologies. In that document, we solicited public input on whether use of the term "fresh" is truthful and nonmisleading in the labeling of foods processed with these technologies and on what criteria we should use when considering use of the term with future technologies. We stated that we would make available at our Dockets Management Branch and on our website the transcript of the public meeting. Also in that document, we stated that interested parties may submit comments to the docket until August 21, 2000.

Following the public meeting, FDA received a comment from a trade association requesting more time for interested parties to comment. The trade association stated that the testimony presented at the public meeting made it evident that the issues surrounding the use of the term "fresh" on foods processed with new technologies are quite complicated. The trade association maintained that additional time is needed for careful consideration of the scientific and technical topics on which FDA is seeking comments. FDA believes that reopening the comment period until November 20, 2000, is appropriate. Reopening the comment period will allow the public adequate time to read the transcript of the public meeting and to carefully consider the topics we are seeking input on before preparing their comments.

II. How To Submit Comments

Interested persons may, on or before November 20, 2000, submit written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or via the FDA Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. Please address your comments to the docket number given at the beginning of this document. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that

you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

Dated: September 12, 2000

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-24123 Filed 9-19-00; 8:45 am]

BILLING CODE 4180-01-F

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[REG-112502-00]

RIN 1545-AY45

Guidance Under Subpart F Relating to Partnerships

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: A notice of proposed rulemaking and notice of proposed rulemaking by cross-reference to temporary regulations published in the *Federal Register* on March 26, 1998, providing guidance under subpart F relating to partnerships and branches, were withdrawn by a notice of proposed rulemaking published in the *Federal Register* on July 13, 1999. This document proposes, with minor changes, the former proposed regulations relating to the treatment of a controlled foreign corporation's distributive share of partnership income. These regulations are necessary to provide guidance on the treatment under subpart F of income earned by a controlled foreign corporation through a partnership. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written comments and outlines of oral comments to be discussed at the public hearing scheduled for December 5, 2000, must be received by November 14, 2000.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG-112502-00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG-112502-00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC. Alternatively,

taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/tax_regs/comments.html. The public hearing will be held in room 4718, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Concerning the regulations, Valerie Mark, (202) 622-3840; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Treena Garrett, (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:**Background**

On March 26, 1998 (63 FR 14613), the IRS issued proposed regulations (REG-104537-97) which contained two sets of provisions, one relating to the treatment under subpart F of a controlled foreign corporation's (CFC's) distributive share of partnership income (including a clarification of the manufacturing exception under the foreign base company sales income rules) and the other relating to hybrid branch transactions. The provisions relating to hybrid branch transactions were also issued as temporary regulations (TD 8767). Congress and taxpayers raised concerns about the proposed and temporary regulations relating to hybrid branch transactions. To respond to these concerns, on July 6, 1998, Treasury and the IRS issued Notice 98-35 (1998-27 I.R.B. 35), which announced that they would withdraw the proposed regulations and remove the temporary regulations. Notice 98-35 also announced that Treasury and the IRS would issue two new separate sets of proposed regulations. One proposed regulation would contain hybrid branch rules. The other proposed regulation would contain rules pertaining to the treatment under subpart F of a CFC's distributive share of partnership income. On July 13, 1999, in furtherance of Notice 98-35, Treasury and the IRS published REG-113909-98 (64 FR 37727), which withdrew the proposed regulations and issued new proposed regulations containing the hybrid branch provisions with new dates of applicability to give Congress and the Treasury more time to evaluate the issues raised by these provisions. On the same date, TD 8827 (64 FR 37677) removed the temporary regulations relating to hybrid branch transactions. Treasury and the IRS are now proposing