persons with a total of 90 days to submit comments before FDA begins work on the final version of the guidance. The agency believes that this 30-day extension allows adequate time for interested persons to submit comments without significantly delaying FDA consideration of these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: February 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2800 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Food Labeling Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas, is announcing a public workshop entitled ''Food Labeling Workshop.'' This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on April 21, 2009, from 8 a.m. to 5 p.m., and on April 22, 2009, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Continuing Education Center, Two East Center St., Fayetteville, AR (located downtown).

Contact: David Arvelo, Small Business Representative, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, or e–mail: *david.arvelo@fda.hhs.gov*.

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or e–mail: *seideman@uark.edu*.

Registration: You are encouraged to register by April 10, 2009. The University of Arkansas has a $250 registration fee to cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $350 payable to: ''The University of Arkansas.'' If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact*) at least 14 days in advance.

Registration Instructions: To register, please submit your name, affiliation, mailing address, phone/fax number, and e–mail, along with a check or money order for $250 payable to the ''The University of Arkansas.'' Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested at cost through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating from the area covered by the FDA Dallas District Office. The SWR SBR presents these workshops to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the SBR Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling requirements, (3) health and nutrition claims, (4) the Food Allergen Labeling and Consumer Protection Act of 2004, and (5) special labeling issues such as exemptions. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and increase voluntary compliance.

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2811 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Food Protection; Public Workshop

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in co-sponsorship with the University of Arkansas Institute of Food

Science and Engineering (IFSE), is announcing a public workshop entitled ''Food Protection Workshop.'' This public workshop is intended to provide information about food safety, food defense, the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and other subjects related to the Food Protection Plan as it relates to food facilities such as farms, manufacturers, processors, distributors, retailers, and restaurants.

Date and Time: This public workshop will be held on May 19 and 20, 2009, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Continuing Education Center, Two East Center St., Fayetteville, AR (located downtown).

Contact Person: Regarding information on accommodation options: Steven C. Seideman, 2650 North Young Ave., Institute of Food Science and Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or email: *seideman@uark.edu.*

Regarding this document and all other information: David Arvelo, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, or e-mail: *david.arvelo@fda.hhs.gov.*

Registration: You are encouraged to register by May 8, 2009. The University of Arkansas has a $250 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed, but it may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $350 payable to: The University of Arkansas. If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact Person*) at least 14 days in advance.

To register, please submit your name, affiliation, mailing address, phone/fax number, and e-mail, along with a check or money order for $250 payable to: The University of Arkansas. Mail to: Institute of Food Science and Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Workshop handouts may be requested at cost through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food protection concerns from food facilities, such as farms, manufacturers, processors, distributors, retailers, and restaurants, originating from the area covered by the FDA Dallas District Office. The Southwest Regional Office presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's guidance, requirements, and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government agencies to small businesses.

The goal of this public workshop is to present information that will enable food facilities (such as farms, manufacturers, processors, distributors, retailers, and restaurants) to better comply with the regulations authorized by the Bioterrorism Act, and with food protection guidance, especially in light of growing concerns about food safety and defense. Information presented will be based on agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Food Defense Awareness, (2) ALERT: The Basics, (3) Employees FIRST, (4) FDA Actions on Bioterrorism Legislation (Food Supply), (5) CARVER+Shock Software Tool, (6) Food Recalls, (7) Crisis Management, (8) Food Protection Technologies and Methodologies, and other related topics. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and guidance perspectives on food protection and increase voluntary compliance and food defense awareness.

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2814 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–M–0522, FDA–2008–M–0425, FDA–2008–M–0426, FDA–2008–M–0478, FDA–2008–M–0402, FDA–2008–M–0437, FDA–2008–M–0477, FDA–2008–M–0467, FDA–2008–M–0501, FDA–2008–M–0515]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead,