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]

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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,

the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2008, through September 30, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2008, THROUGH SEPTEMBER 30, 2008.

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P060037 FDA–2008–M–0522	Zimmer, Inc.	NEXGEN LPS–FLEX MOBILE & LPS MOBILE BEARING KNEE SYSTEM	December 10, 2007
P850048 (S021) FDA–2008–M–0425	Beckman Coulter, Inc.	ACCESS HYBRITECH PSA REAGENTS	May 9, 2008
P060027 FDA–2008–M–0426	ELA Medical, Inc.	OVATIO CRT–D SYSTEM	May 15, 2008
P060039 FDA–2008–M–0478	Medtronic Cardiac Rhythm Disease Management	ATTAIN STARFIX MODEL 4195 LEAD	June 13, 2008
P070013 FDA–2008–M–0402	Colbar Lifescience Ltd.	EVOLENCE COLLAGEN FILLER	June 27, 2008
P050040 FDA–2008–M–0437	Invitrogen Corporation	SPOT–LIGHT HER2 CISH KIT	July 1, 2008
P070006 FDA–2008–M–0477	Oxford Immunotec, Ltd.	T SPOT–TB TEST	July 30, 2008
P040037 (S007) FDA–2008–M–0467	W.L. Gore & Associates, Inc.	VIABAHN ENDOPROSTHESIS	August 14, 2008
P050028 FDA–2008–M–0501	Roche Molecular Systems, Inc.	COBAS TAQMAN HBV TEST	September 4, 2008
P060022 FDA–2008–M–0515	Bausch & Lomb, Inc.	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS	September 5, 2008

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: January 15, 2009.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E9–2685 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]

Science Board to the Food and Drug Administration; 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 Committee: Science Board to the Food and Drug Administration (Science Board).

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

Date and Time: The meeting will be held on Tuesday, February 24, 2009, from 8 a.m. to 3 p.m.

Addresses: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, or