

the other drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 012524 .....	ENDURON (methyclothiazide) Tablets, 2.5 milligrams (mg) and 5 mg.	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064–3500.
NDA 016949 .....	LIMBITROL and LIMBITROL DS (amitriptyline hydrochloride; chlordiazepoxide) Tablets, equivalent to (EQ) 12.5 mg (base), 5 mg, and EQ 25 mg (base), 10 mg.	Valeant Pharmaceuticals International, Inc., 4787 Levy St., Montreal, Quebec H4R 2P9, Canada.
NDA 017577 .....	DITROPAN (oxybutynin chloride) Tablets, 5 mg .....	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560.
NDA 017950 .....	WESTCORT (hydrocortisone valerate) Cream, 0.2% ....	Ranbaxy Laboratories, Ltd., 600 College Road East, suite 2100, Princeton, NJ 08540.
NDA 018763 .....	TOPICORT (desoximetasone) Ointment, 0.25% .....	Taro Pharmaceuticals, Inc., 3 Skyline Dr., Hawthorne, NY 10532.
NDA 020036 .....	AREDIA (pamidronate disodium) Injection, 30 mg/vial ..	Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936–1080.
NDA 020038 .....	FLUDARA (fludarabine phosphate) Injection, 50 mg/vial	Genzyme Corporation, 1850 K St. NW., suite 650, Washington, DC 20006.

FDA has reviewed its records and, under 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 24, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–23779 Filed 9–26–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–N–0001]

#### Food Defense; 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), Southwest Regional Office (SWRO), in co-sponsorship with Oklahoma State University (OSU), Robert M. Kerr Food & Agricultural Products Center (FAPC), is announcing a public workshop entitled “Food Defense Workshop.” This public workshop is intended to provide information about food defense 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 November 7 and 8, 2012, from 7:45 a.m. to 4:15 p.m.

**Location:** The public workshop will be held at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078–6055.

**Contact:** For information regarding the workshop: 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, email: [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

**For information on accommodations:** Karen Smith or Andrea Graves at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078–6055, 405–744–6277, Fax: 405–744–6313, or email: [karenl.smith@okstate.edu](mailto:karenl.smith@okstate.edu) or [andrea.graves@okstate.edu](mailto:andrea.graves@okstate.edu). More information is also available online at <http://www.fapc.biz/fooddefense2012.html>.

**Registration:** You are encouraged to register by October 31, 2012. The workshop has a registration fee to cover the cost of facilities, materials, speakers, and breaks. The registration fee is \$350 for companies with 10 or more

employees or \$250 for companies with less than 10 employees. Seats are limited; please submit your registration as soon as possible. To register, please complete the online registration form at <http://www.fapc.biz/fooddefense2012.html>. The workshop will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop 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 7:45 a.m. Make checks payable to: “FAPC.” If you need special accommodations due to a disability, please contact Karen Smith (see *Contact*) at least 7 days in advance. There are no registration fees for FDA employees.

**Transcripts:** Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested after the date of the public workshop by contacting Karen Smith or Andrea Graves (see *Contact*) at cost plus shipping.

**SUPPLEMENTARY INFORMATION:** This public workshop is being held in response to the large volume of food defense inquiries from food manufacturers 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, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's guidance. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as outreach activities by Government Agencies to small businesses.

The goal of this public workshop is to present information that will enable regulated industry to better comply with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and to better understand FDA's food defense guidance, especially in light of growing concerns about food protection. 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 the following:

- Food defense awareness and definitions,
- FDA food defense tools such as ALERT and Employees FIRST,
- Regulations mandated by the Bioterrorism Act,
- Food Defense Guidance from the Food Safety and Inspection Service,
- Investigating food-related incidents effectively,
- Physical plant security,
- Crisis management, and
- A food related emergency exercise bundle (FREE-B) tabletop exercise on food defense.

For more information, please visit <http://www.fapc.biz/fooddefense2012.html>. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency's regulatory and policy perspectives on food protection, increase compliance with FDA regulations, and heighten food defense awareness.

Dated: September 21, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-23778 Filed 9-26-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing—Clinical Trials & Translational Research.

*Date:* October 19, 2012.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496-8683, [livingsc@mail.nih.gov](mailto:livingsc@mail.nih.gov).

*Name of Committee:* National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Vestibular—Clinical Trials.

*Date:* October 23, 2012.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496-8683, [livingsc@mail.nih.gov](mailto:livingsc@mail.nih.gov).

*Name of Committee:* National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Chemosensory Fellowship Application Review.

*Date:* October 24, 2012.

*Time:* 10:30 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Andrea B. Kelly, Ph.D., Scientific Review Officer, Division of

Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Rockville, MD 20892, (301) 496-8683, [kellya2@nidcd.nih.gov](mailto:kellya2@nidcd.nih.gov).

*Name of Committee:* National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Auditory—CNS Stimulation & Prosthesis Clinical Trials.

*Date:* October 25, 2012.

*Time:* 9 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892 (301) 496-8683, [livingsc@mail.nih.gov](mailto:livingsc@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: September 21, 2012.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute On Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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

The meeting 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 Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA AA-1 Member Conflict Applications.

*Date:* October 9, 2012.

*Time:* 2:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* NIAAA, Rockville, MD, (Telephone Conference Call).

*Contact Person:* Richard A Rippe, Ph.D., Scientific Review Officer, National Institute