

- California will increase the number of participants attending the Border Health Research Forum and will host a stakeholders meeting in support of the Prevention and Health Promotion among Vulnerable Populations on the U.S.-Mexico Border Initiative.

- Texas will increase the number of participants attending the Border Binational Obesity Prevention Summit, to share knowledge and best practices regarding a critical problem affecting border populations.

- New Mexico will plan, coordinate, and execute Phase IV of the Healthy Border 2010/2020 Strategic Plan, and will increase the number of regional activities of the Prevention and Health Promotion among Vulnerable Populations on the U.S.-Mexico Border Initiative, to improve health outcomes of vulnerable populations living on the U.S.-Mexico Border.

## II. Award Information

The administrative and funding instrument to be used for this program will be cooperative agreements in which substantial OGA/HHS scientific and/or programmatic involvement is anticipated during the performance of these projects. Under the cooperative agreements, OGA/HHS will support and/or stimulate awardees activities by working with them in a non-directive partnership role. Awardees will also be expected to work directly with and in support of the U.S.-Mexico Border Health Commission and its stated goals and initiatives as outlined in the submitted work plan.

Approximately \$150,000.00 (\$37,500.00 to each State) in fiscal year (FY) 2012 funds are available as supplemental funding to the already existing agreements. The anticipated start date is September 30, 2012 through August 31, 2013. There will only be four awards made from this announcement.

## III. Justification for the Exception to Competition

The supplemental funding is for ongoing, cooperative agreements already awarded to the border health offices in the States of California, Arizona, New Mexico, and Texas. The purpose of the activities of the cooperative agreements is to accomplish the goals and objectives of the US-Mexico Border Health Commission. State border health offices have both extensive experience working with the Border Health Commission, and have existing relationships and ongoing initiatives with Mexican border states. This experience and relationships make the offices unique in helping the Commission carry out its

binational health initiatives and activities along the border.

The supplemental funds are to provide additional support for several key activities of the cooperative agreements. Because the activities are ongoing, and being planned and carried out by the State border health offices, awarding the funds to the border health offices is the only practicable way to accomplish the objectives of enhancing and extending the activities.

## IV. Agency Contacts

For programmatic requirements, please contact: Craig Shapiro MD, Office of Global Affairs, DHHS, Mary E. Switzer Building, 330 C Street, SW., Washington, DC 20201, Phone: (202) 260-0399.

For administrative requirements please contact: Alice Bettencourt, Director, Office of Grants Management, Office of the Assistant Secretary for Health, 1101 Wotton Parkway, Suite 550, Rockville, MD 20852, Telephone: (240) 453-8822.

Dated: September 20, 2012.

**Jimmy Kolker,**

*Principal Deputy Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0190]

### Determination That ENDURON (methyclothiazide) Tablets and Six Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that the seven drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Mark Geanacopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, rm. 6206, Silver Spring, MD 20993-0002, 301-796-6925.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

As requested by the applicants, FDA withdrew approval of NDA 012524 for Enduron (methyclothiazide) Tablets and NDA 017577 for Ditropan (oxybutynin chloride) Tablets in the **Federal Register** of March 19, 2012 (77 FR 16039). In addition, FDA has become aware that

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.*

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## 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