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Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Emergency Funding for New York City Legionella Outbreak

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice.

SUMMARY: The U.S. Centers for Disease Control and Prevention (CDC) is providing \$1,300,000 in urgent funding through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement to the New York City Department of Health (NYC HD) to combat an outbreak of *Legionella*. As of August 18, 2015 NYC HD has identified 127 cases and 12 deaths associated with this public health emergency. These funds will be used by NYC HD to (1) create sustainable environmental and laboratory capacity at NYC HD to respond to *Legionella* outbreak, (2) enhance laboratory capacity of detection, isolation, and molecular characterization of clinical and environmental strains at the New York City public health laboratory, (3) include sequence-based typing and eventually whole genome sequencing, and (4) allow NYC HD to characterize the geographic distribution of *Legionella* strains throughout New York City, support the new public health engineering program to monitor the compliance of building owners with the new cooling tower regulations, and work with CDC to evaluate the impact of these regulations.

DATES: Effective date is date of publication in the **Federal Register**.

ADDRESSES: Alvin Shultz, MSPH, Division of Preparedness and Emerging Infectious, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and

Prevention, 1600 Clifton Road NE., Atlanta, GA 30333, Phone: 404-639-7028, E-Mail: Ashultz@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Alvin Shultz, MSPH, Division of Preparedness and Emerging Infectious, National Center for Emerging and Zoonotic Infectious, Diseases Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782 Phone: 301-458-4371, FAX: 301-458-4028, E-Mail: NHANESgenetics@cdc.gov.

Dated: September 23, 2015.

Terrance Perry,

Director, Office of Grants Services, Centers for Disease Control and Prevention.

[FR Doc. 2015-24564 Filed 9-25-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3275]

Labeling Lower-Dose Estrogen-Alone Products for Symptoms of Vulvar and Vaginal Atrophy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on the topic of the labeling for lower-dose estrogen products delivered vaginally, intended to treat moderate to severe symptoms of vulvar and vaginal atrophy (VVA) due to menopause. Lower-dose estrogen products means products that contain less than the 0.625 milligrams (mg) of conjugated estrogens used in the Women's Health Initiative Study, and estradiol products containing 0.0375 mg and below. Lower-dose estrogen products are now approved for the treatment of moderate to severe symptoms of VVA due to menopause, and some in the scientific/medical community have questioned whether the current "Boxed Warnings" section in the labeling is applicable in whole or in part to these lower-dose estrogen products. This meeting, a scientific workshop, will provide an opportunity for FDA to seek input from experts on the Boxed Warnings section, estrogen exposure data, and pharmacokinetic (PK)/pharmacodynamic (PD) relationships relative to labeling lower-dose estrogen-alone products intended

to treat moderate to severe symptoms of VVA due to menopause.

DATES: The public meeting will be held on November 10, 2015, from 8:30 a.m. to 5 p.m. Registration to attend the meeting must be received by October 16, 2015, with onsite registration available between 7 a.m. and 8 a.m. the day of the meeting. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for this meeting. Submit either electronic or written comments by October 16, 2015.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm459690.htm>.

FOR FURTHER INFORMATION CONTACT: Kimberly Shiley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 5377, Silver Spring, MD 20993, 301-796-2117, email: Kimberly.Shiley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The loss of ovarian function with menopause leads to a drastic reduction in circulating estrogen concentration, which in turn leads to physiologic changes to the vulva, vagina, and lower urinary tract. Reduced circulating estrogen concentration results in an increase in vaginal pH, a thinning and reduction of the folds of the vaginal lining, reduction of vaginal secretions, and loss of elasticity in vaginal tissues. Symptoms of decreased circulating estrogen include vaginal and vulvar itching and/or irritation, vaginal dryness and vaginal pain (dyspareunia), and/or bleeding with intercourse. Not all