

contract amount is expected to exceed \$650,000 and the service to be provided will require meaningful numbers of professional employees. The purpose of the provision at FAR 52.222-46 is to require offerors to submit for evaluation a total compensation plan setting forth proposed salaries and fringe benefits for professional employees working on the contract. Plans indicating unrealistically low professional employees' compensation may be assessed adversely as one of the factors considered in making a contract award.

### B. Annual Reporting and Recordkeeping Burden

*Respondents:* 12,921.

*Responses per Respondent:* 3.

*Total Responses:* 38,763.

*Hours per Response:* 1.333333.

*Total Burden Hours:* 51,684.

### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

#### *Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755.

Please cite OMB Control No. 9000-0066, Professional Employee Compensation Plan, in all correspondence.

#### **Edward Loeb,**

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

[FR Doc. 2015-24557 Filed 9-25-15; 8:45 am]

**BILLING CODE 6820-EP-P**

## DEPARTMENT OF DEFENSE

### GENERAL SERVICES ADMINISTRATION

### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2015-0055; Sequence 19; OMB Control No. 9000-0080]

### Submission for OMB Review; Integrity of Unit Prices

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Integrity of Unit Prices. A notice was published in the **Federal Register** at 80 FR 35359 on June 19, 2015. One comment was received, but was unrelated to the subject matter.

**DATES:** Submit comments on or before October 28, 2015.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000-0080, Integrity of Unit Prices". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000-0080, Integrity of Unit Prices" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street WE, Washington, DC 20405. ATTN: Ms. Flowers/IC 9000-0080, Integrity of Unit Prices.

*Instructions:* Please submit comments only and cite Information Collection 9000-0080, Integrity of Unit Prices, in

all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:** Mr. Edward Loeb, Procurement Analyst, Office of Acquisition Policy, GSA, 202-501-0650 or email [edward.loeb@gsa.gov](mailto:edward.loeb@gsa.gov).

### SUPPLEMENTARY INFORMATION:

#### A. Purpose

The clause at FAR 52.215-14, Integrity of Unit Prices, requires offerors and contractors under Federal contracts that are to be awarded without adequate price competition to identify in their proposals those supplies which they will not manufacture or to which they will not contribute significant value. The policies included in the FAR are required by 41 U.S.C. 3503 (a)(1)(A)(for the civilian agencies) and 10.U.S.C 2306a(b)(1)(A)(i)(for DOD and NASA). The rule contains no reporting requirements on contracts below the simplified acquisition threshold, construction and architect-engineering services, utility services, service contracts where supplies are not required, commercial items, and contracts for petroleum products.

#### B. Annual Reporting Burden

*Respondents:* 950.

*Responses per Respondent:* 10.

*Annual Responses:* 9,500.

*Hours per Response:* 1.

*Total Burden Hours:* 9,500.

#### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

#### *Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from

the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202501-4755. Please cite OMB Control No. 9000-0080, Integrity of Unit Prices.

**Edward Loeb,**

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

[FR Doc. 2015-24559 Filed 9-25-15; 8:45 am]

**BILLING CODE 6820-EP-P**

**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](mailto: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](mailto: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]

**BILLING CODE 4163-18-P**

**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](http://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](mailto: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