

contracts awarded annually at \$100,000 or more, of which 65 percent or 11,375 contracts will be competitively awarded. About 7 proposals will be received for each contract award. Of the total 79,625 (11,375 × 7) proposals received, only 25 percent or 19,906 proposals are expected to include uncompensated overtime hours. It is estimated that offerors will take about 30 minutes to identify and support any hours in excess of 40 hours per week included in their proposal or subcontractor's proposal.

*Number of Respondents:* 19,906.

*Responses Per Respondent:* 1.

*Total Annual Responses:* 19,906.

*Average Burden Hours Per Response:* .5.

*Total Burden Hours:* 9,953.

### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and 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. 9000-0152, Service Contracting, in all correspondence.

Dated: July 20, 2015.

**Edward Loeb,**

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

[FR Doc. 2015-18077 Filed 7-22-15; 8:45 am]

**BILLING CODE 6820-EP-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Clinical Laboratory Improvement Advisory Committee: Notice of Charter Amendment

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has amended their charter to reduce the number of annual meetings and to change the designation of CDC, FDA and CMS from voting to non-voting ex officio members. The amended filing date is July 9, 2015.

For information, contact Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Programs, Standards, and Services, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, CDC, 1600 Clifton Road, NE., Mailstop F-11, Atlanta, Georgia 30329-4018; telephone (404) 498-2741.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2015-18065 Filed 7-22-15; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC)

*Correction:* This notice was published in the **Federal Register** on June 16, 2015, Volume 80, Number 115, Page 34435. The Matters For Discussion and Contact Person For More Information should read as follows:

*Matters For Discussion:* The BSC, NCIPC will discuss, research strategies needed to guide the Center's focus, updates on the current research

portfolio review and the Pediatric mild-Traumatic Injury Workgroup. There will be 15 minutes allotted for public comments at the end of the open session.

On the second day, the BSC, NCIPC will meet to conduct a Secondary Peer Review of extramural research grant applications received in response to four (4) Funding Opportunity Announcements (FOAs): PHS 2014002 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR {R42/R44}); CE15-003, Evaluating Structural, Economic, Environmental, or Policy Primary Prevention Strategies for Intimate Partner Violence and Sexual Violence; CE15-004, Evaluating Innovative and Promising Strategies to Prevent Suicide among Middle-Aged Men; and CE15-005, Research to Evaluate the CDC Heads Up Initiative in Youth Sports. Applications will be assessed as they relate to the Center's mission and programmatic balance. Recommendations from the secondary review will be voted upon and the application will be forwarded to the Center Director for consideration for funding support.

*Contact Person For More Information:* Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, Acting Designated Federal Officer, NCIPC, CDC, 4770 Buford Highway NE., Mailstop F-63, Atlanta, GA 30341, Telephone (770) 488-1279.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office Centers for Disease Control and Prevention.*

[FR Doc. 2015-18064 Filed 7-22-15; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-2523]

#### Intent To Review a Study Data Reviewer's Guide Template

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

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is establishing a public docket to collect comments related to a proposed Study Data Reviewer's Guide (SDRG) template. As part of FDA's ongoing collaboration with the Pharmaceutical Users Software Exchange (PhUSE), an independent, non-profit consortium addressing computational science issues, a PhUSE working group developed the PhUSE SRDG template. The purpose of this review is to evaluate the template and determine whether FDA will recommend its use either as is, or in a modified form, for regulatory submissions of study data. FDA is seeking public comment on the use of the PhUSE SDRG template for regulatory submissions.

**DATES:** Although you can comment on the PhUSE SRDG template at any time, to ensure that the Agency considers your comments in this review, please submit either electronic or written comments by September 21, 2015.

**ADDRESSES:** Submit written requests for single copies of the PhUSE SDRG template to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to <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.

**FOR FURTHER INFORMATION CONTACT:** Crystal Allard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 1518, Silver Spring, MD 20993-0002, 301-796-8856, [crystal.allard@fda.hhs.gov](mailto:crystal.allard@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is a participating member of PhUSE, an independent, non-profit consortium of academic, regulatory, non-profit, and private sector entities. PhUSE provides a global platform for the discussion of topics encompassing the work of biostatisticians, data managers, statistical programmers, and e-clinical information technology

professionals, with the mission of providing an open, transparent, and collaborative forum to address computational science issues. As part of this collaboration, PhUSE working groups develop and periodically publish proposals for enhancing the review and analysis of human and animal study data submitted to regulatory agencies. You can learn more about PhUSE working groups at <http://www.phuse.eu/cs-working-groups.aspx>.

In December 2014, FDA published the Study Data Technical Conformance Guide (the "Guide," available at <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>), which contains technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format. In section 2.2 of the Guide, FDA recommends that each submitted study contain a Study Data Reviewer's Guide containing any special considerations or directions that may facilitate review of the study data. FDA notes in the Guide that the PhUSE SDRG template is an example of how to create an SDRG, but does not specifically recommend its use.

FDA now intends to review the PhUSE SDRG template, a deliverable of the working group effort described above, with the potential result that FDA could recommend the use of the template in its current form, or in a modified form, for use in the regulatory submission of study data in conformance with the Guide. FDA invites public comment on all matters regarding the use of the PhUSE SDRG template. Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

##### **II. Electronic Access**

The PhUSE SDRG template is available online at [http://www.phusewiki.org/wiki/index.php?title=Study\\_Data\\_Reviewer's\\_Guide](http://www.phusewiki.org/wiki/index.php?title=Study_Data_Reviewer's_Guide).

Dated: July 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-18027 Filed 7-22-15; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-N-0781]

#### **Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled, "Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On June 08, 2015, the Agency submitted a proposed collection of information entitled, "Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0428. The approval expires on July 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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