DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0001]

The Food and Drug Administration/ National Heart Lung and Blood Institute/ National Science Foundation Workshop on Computer Methods for Cardiovascular Devices: The Integration of Nonclinical and Clinical Models; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled “FDA/NHLBI/NSF Workshop on Computer Methods for Cardiovascular Devices: The Integration of Nonclinical and Clinical Models.” The workshop will include a smaller, optional session entitled “Microstructure Modeling Session.” FDA is cosponsoring the workshop with the National Heart Lung and Blood Institute of the National Institutes of Health and the National Science Foundation. The purpose of the workshop is to facilitate discussion between FDA and other interested parties on the use of computational modeling in cardiovascular device design, development, and evaluation.

Dates and Times: The optional session will be held on June 9, 2010, from 1 p.m. to 5:30 p.m. and the public workshop will be held on June 10 and 11, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop and optional session will be held at the Hilton Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Donna R. Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1110, Silver Spring, MD 20993, 301–796–6315, donna.lochner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion between FDA and other interested parties on the use of computational modeling in cardiovascular device design, development, and evaluation.

II. What Are the Topics We Intend to Address at the Public Workshop?

We hope to discuss a large number of issues at the public workshop, with our overall theme being the integration of computer and nonclinical models. Topics include, but are not limited to the following:

• Multiscale, multiphysics, and multiphase modeling;
• Modeling of cardiovascular diseases and therapies;
• Patient-specific modeling, including virtual surgical planning and predictive biomedicine;
• Open source projects, including public policy initiatives, database development and data presentation, and standards and protocols; and
• Regulatory issues with implementation of computer modeling.

III. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at http://www.fda.gov/
SUPPLEMENTARY INFORMATION section for electronic access to the SECG.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 9, 2009 (74 FR 33030), FDA issued a final rule requiring shell egg producers to implement measures to prevent Salmonella Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the rule and to register with FDA. The final rule became effective September 8, 2009.

FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the requirements of the regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents FDA’s current thinking on the prevention of SE in shell eggs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This SECG refers to collections of information described in FDA’s final rule that published in the Federal Register of July 9, 2009 (74 FR 33030 at 33089), and that became effective on September 8, 2009. As stated in the final rule, these collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of the final rule to OMB for review. FDA will publish a notice in the Federal Register announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments regarding this SECG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The SECG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/FoodGuidances or http://www.regulations.gov.

Dated: April 7, 2010.

Leslie Kux.,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2009–0026]

National Protection and Programs Directorate; Chemical Facility Anti-Terrorism Standards Personnel Surety Program

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-day notice and request for comments: New information collection request 1670–NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP), Infrastructure Security Compliance Division (ISCD) will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is a new information collection. A 60-day public notice for comments was previously published in the Federal Register on June 10, 2009, at 74 FR 27555.

Comments were received and responses are in this notice. The purpose of this notice is to solicit additional comments during a 30-day public comment period prior to the submission of this collection to OMB. The submission describes the nature of the information collection, the categories of respondents, the estimated burden, and cost.

DATES: Comments are encouraged and will be accepted until May 13, 2010. This process is conducted in accordance with 5 CFR 1320.8.

ADDRESSES: Interested persons are invited to submit comments on the proposed information collection through the Federal Rulemaking Portal at http://www.regulations.gov. Follow the instructions for submitting comments. Comments must be identified by docket number DHS–2009–0026.

Comments that include trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI), Sensitive Security Information (SSI), or Protected Critical Infrastructure Information (PCI) should not be submitted to the public regulatory docket. Please submit such comments separately from other comments in response to this notice. Comments containing trade secrets, confidential commercial or financial information, CVI, SSI, or PCI should be appropriately marked and submitted by mail to the DHS/NPPD/IP/ISCD CFATS Program Manager at the Department of Homeland Security, 245 Murray Lane, SW., Mail Stop 0610, Arlington, VA 20528–0610. Comments must be identified by docket number DHS–2009–0026.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained through the Federal Rulemaking Portal at http://www.regulations.gov.

SUPPLEMENTARY INFORMATION:

Program Description

The Chemical Facility Anti-Terrorism Standards (CFATS), 6 CFR part 27, require high-risk chemical facilities to submit information about facility personnel and, as appropriate, unescorted visitors with access to restricted areas or critical assets at those facilities. This information will be vetted by the Federal Government against the Terrorist Screening Database (TSDB), the consolidated and integrated terrorist watchlist maintained by the Federal Government, to identify known or suspected terrorists (i.e., individuals with terrorist ties).