Dated: April 8, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–8426 Filed 4–12–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Preparation for International Conference on Harmonisation Steering Committee and Expert Working Group Meetings in Tallinn, Estonia; Regional Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Steering Committee and Expert Working Group Meetings in Tallinn, Estonia" to provide information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Tallinn, Estonia. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Tallinn, Estonia, June 5 through 10, 2010, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on Wednesday, May 5, 2010, from 2:30 p.m. to 4:30 p.m.

Location: The meeting will be held at the Washington Theater at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: All participants must register with Jennifer Haggerty, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: *jennifer.haggerty@fda.hhs.gov* or FAX: 301–827–0003.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentations, to the contact person by April 30, 2010.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 4 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 30, 2010, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available via the Internet at: *http://www.fda.gov/Drugs/NewsEvents/ucm204924.htm*.

If you need special accommodations due to a disability, please contact Jennifer Haggerty at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufactures Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area, and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Dated: April 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8379 Filed 4–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Prevention Research Centers Comparative Effectiveness Research Program, DP 10–003, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates: 8:30 a.m.–6 p.m., May 4, 2010 (Closed); 8:30 a.m.–5 p.m., May 5, 2010 (Closed).

Place: W Hotel, 1111 Perimeter Center W., Atlanta, GA 30346.

Telephone: (770) 396–6800.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Prevention Research Centers Comparative Effectiveness Research Program, DP 10–003."

Contact Person for More Information: Donald Blackman, PhD, Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program

Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, GA 30341, *Telephone:* (770) 488–3023, *E-mail: DYB7@cdc.gov.*

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 5, 2010.

Elaine L. Baker,

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

[FR Doc. 2010–8442 Filed 4–12–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

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 the design, development, and evaluation of cardiovascular medical devices.

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, 301–796–6309, *donna.lochner@fda.hhs.gov*.

Registration: To register for the public workshop and optional session, please visit the following Web site: *http://scpd.stanford.edu/publicViewHome.do?method=load*. There is a registration fee to attend the public workshop to cover the expenses and attendees must register in advance. The fee for the meeting is $350. Students will be offered a discounted fee of $175. The exhibitors' fee is $600 and includes registration of one person. Fees will be waived for invited speakers and the organizing committee. The registration process will be handled by the Stanford Center for Professional Development. Although the facility is spacious, registration will be on a first-come, first-served basis.

If you need special accommodations because of a disability, please contact Donna R. Lochner at least 7 days before the public workshop.

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/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*

Dated: April 7, 2010.

Jeffrey Shuren,

Director, Center for Devices and Radiological Health.

[FR Doc. 2010–8311 Filed 4–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0183]

Small Entity Compliance Guide: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation—Small Entity Compliance Guide." The small entity compliance guide (SECG) is being issued for a final rule published in the **Federal Register** of July 9, 2009, and is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation. Elsewhere in this issue of the **Federal Register**, FDA is amending its July 9, 2009, regulation to correct the date by which producers must register their farm with FDA, reflect a change in the address and telephone number for requesting copies of Form No. 3733, and reflect a change in the address to which producers must send their CD–ROM.

DATES: Submit electronic or written comments on the SECG at any time.

ADDRESSES: Submit electronic comments on the SECG to *http://www.regulations.gov*. Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the SECG to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–1070. Send two self-addressed adhesive labels to assist that office in processing your request. See the