''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement. The guidance represents agency's current thinking on the topic. 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 applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 1–5 of the guidance have been approved under OMB control no. 0910–0032 (expiration date April 30, 2010).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: April 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9521 Filed 4–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control, Initial Review Group, (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting of the aforementioned review group:

Times and Dates:

8 a.m.–8:15 a.m., April 27, 2009 (Open).

8:15 a.m.–4 p.m., April 27, 2009 (Closed).

Place: Teleconference, Toll Free Number: (877) 468–4185, Participant Pass code: 447–5689.

Status: Portions of the meetings 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 Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications submitted in response to Fiscal Year 2009 Requests for Applications related to the following individual research announcement: CE09–009, Youth Violence Prevention through Economic, Environmental, and Policy Change (U01).

Agenda items are subject to change as priorities dictate.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

Contact Person for More Information: Lisa T. Garbarino, B.S., NCIPC, Extramural Research Program Office, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, Georgia 30341–3724, *Telephone:* (404) 723–1527.

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 21, 2009.

Elaine L. Baker,

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

[FR Doc. E9–9503 Filed 4–24–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Computational Modeling for Cardiovascular Devices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Computational Modeling for Cardiovascular Devices.'' FDA is co-sponsoring the conference with the National Heart, Blood and Lung Institute of the National Institutes of Health and the National Science Foundation. The purpose of the public workshop is to facilitate discussion among FDA and other interested parties on the use of computational modeling in the design, development, and evaluation of cardiovascular medical devices.

Date and Time: The public workshop will be held on June 1 and 2, 2009, from 8 a.m. to 5 p.m.

Location: The public workshop 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 (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4043, e-mail: *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 among 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, including, but not limited to:

- Multi-scale modeling.
- Imaging for cardiovascular device modeling.
- Physiologic input data for cardiovascular device modeling.
- Device-specific issues related to modeling, including a focus on heart valves, drug-eluting and bare metal stents, endovascular stents, cardiac rhythm management, and mechanical and circulatory support devices.