agency's current thinking on this 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 alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection of information in this guidance was approved under OMB control no. 0910–0635.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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.

IV. Electronic Access

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

Dated: July 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16702 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0312]

Guidance for Institutional Review Boards, Frequently Asked Questions—Institutional Review Board Registration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions — IRB Registration.'' This guidance is intended to assist IRBs in complying with the new requirement for IRB registration. This new rule requires each IRB in the United States that reviews FDA-regulated research to register using an Internet-based registration system that is maintained by the Department of Health and Human Services (HHS). This registration system is a modification of the one currently used by the Office for Human Research Protections (OHRP) for registration of IRBs that are designated by institutions under Federalwide Assurances (FWAs). OHRP has issued a similar rule requiring IRBs designated by institutions under FWAs to register or update their registration information using this modified system.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jean Toth-Allen, Office of Science and Health Coordination/Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document for IRBs entitled, ''Guidance for Institutional Review Boards (IRBs), Frequently Asked Questions — IRB Registration.'' This guidance is intended to assist IRBs in complying with the new requirement for IRB registration under amended 21 CFR 56.106, which is effective July 14, 2009. Registration will be accomplished through a modified version of the Internet-based registration system used by OHRP for registration of IRBs that are designated by institutions under FWAs. This guidance document addresses basic information, such as why FDA issued the new rule, which IRBs are subject to the new regulation, the type of information to be provided when registering, and implications of non-compliance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is being issued as a level 1 guidance for immediate implementation in accordance with 21 CFR 10.115(g). Prior public participation is not feasible and FDA believes the guidance is necessary to help IRBs better understand their responsibilities under the new registration rule, which will go into effect on July 14, 2009.

II. The Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information required by the FDA new final rule on registration requirements. This collection of information is 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 collection of information in 21 CFR 56.106(b) has been approved under 0990–0279.

III. Comments

Interested persons may submit written or electronic comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/gcp/draft.html* or *http://www.fda.gov/ohrms/dockets/default.htm*

Dated: July 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16703 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,