combination drugs) containing old antibiotics by December 5, 2008.[1] The draft guidance describes FDA's current thinking on the implementation of section 4(b)(1) of the Q1 Act and addresses which sponsors of NDAs must submit patent information to the agency under section 4(b)(1) of the Q1 Act by December 5, 2008.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the submission of patent information under section 4(b)(1) of the Q1 Act. 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. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 21 CFR 314.50(h) and 314.53 have been approved under OMB control number 0910–0513.

IV. Electronic Access

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

Dated: November 26, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28657 Filed 12–2–08; 8:45 am]

BILLING CODE 4160–01–S

[1] Section 4(b)(1) of the Q1 Act requires the submission of patent information to FDA ''not later than sixty days after enactment of [the Q1 Act].'' Sixty days after enactment falls on Sunday, December 7, 2008. Therefore, to be in compliance with this provision, sponsors must submit the patent information on or before the weekday preceding December 7, 2008, that is, on or before December 5, 2008.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences, Special Emphasis Panel, Large-Scale Collaborative Project Awards (U54).

Date: December 22, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Lisa Dunbar, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–594–2849, *dunbarl@mail.nih.gov*. (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 21, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–28509 Filed 12–2–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; Extension, without change, of a currently approved collection, OMB Number 1660–0024, No Form.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Collection of Information

Title: Federal Assistance for Offsite Radiological Emergency Planning.

OMB Number: 1660–0024.

Abstract: In accordance with Executive Order 12657, FEMA will need certain information from the licensee (the utility which has applied for or received a license from the Nuclear Regulatory Commission (NRC) to operate a nuclear power plant) in order to form a decision, based on the advice of the NRC, as to whether or not a condition of ''decline or fail'' exists on the part of State or local governments (44 CFR 352.3–4). This information will be collected by the appropriate FEMA Regional Office or Headquarters.

Affected Public: Business or other for-profit.

Number of Respondents: 1.

Estimated Time per Respondent: 160 hours.

Estimated Total Annual Burden Hours: 160 hours.

Frequency of Response: Once.

Comments: Interested persons are invited to submit written comments on