directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We estimate that FY 2009 IPPS payments will increase approximately $3 million based on the changes included in this notice. Therefore, we note that not only does this notice not constitute a substantive rule, but it also does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the notice is not a substantive rule, and we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately $130 million. This notice will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

**Authority:** (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: November 20, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: *November 25, 2008.*

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. E8–28619 Filed 12–2–08; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0609]**

### Draft Guidance for Industry on the Submission of Patent Information for Certain Old Antibiotics; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Patent Information for Certain Old Antibiotics.'' The draft guidance describes the agency's current thinking on the implementation of certain provisions of the Q1 Program Supplemental Funding Act (the Q1 Act) that concern old antibiotics and addresses which sponsors of new drug applications (NDAs) must submit patent information under the Q1 Act by December 5, 2008.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 2, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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 draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Mary Ann Holovac, Center for Drug Evaluation and Research (HFD–615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8971.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Patent Information for Certain Old Antibiotics.'' The draft guidance provides information regarding FDA's current thinking on the implementation of section 4(b)(1) of the Q1 Act (Public Law 110–379).

The Q1 Act amends section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) by adding subsection (v), which establishes, among other things, certain conditions under which the patent listing, patent certification, and marketing exclusivity provisions of sections 505(c) and (j) of the FD&C Act, and the patent term extension provisions of 35 U.S.C. 156 apply to marketing applications for drugs that contain an antibiotic that was the subject of any marketing application received by FDA on or before November 20, 1997 (an old antibiotic). The transitional rules at section 4(b) of the Q1 Act provide for the submission of the patent information by sponsors of certain NDAs, the publication of such patent information by FDA, and the certification to such patents by applicants of pending abbreviated new drug applications to be deemed ''a first applicant'' (as defined in section 505(j)(5)(B)(iv) the FD&C Act), not later than 60, 90, and 120 days after enactment of the Q1 Act, respectively.

Specifically, section 4(b)(1) of the Q1 Act requires the submission to FDA of patent information by sponsors of certain NDAs for drugs (including

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