combination drugs) containing old antibiotics by December 5, 2008.[1] The draft guidance describes FDA's current thinking on the implementation of section 4(b)(1) of the Q1 Act and addresses which sponsors of NDAs must submit patent information to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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the submission of patent information under section 4(b)(1) of the Q1 Act.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This draft guidance refers to previously approved collections of information found in FDA regulations.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

the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–6974. Comments must be submitted on or before January 2, 2009.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Acting Director, Records Management Division, 500 C Street, SW., Washington, DC 20472, Mail Drop Room 301, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov.*

Lawann Johnson,

Acting Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E8–28688 Filed 12–2–08; 8:45 am]

BILLING CODE 9110–21–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–R–2008–N0204; 50133–1265–LKUP; S3]

Lake Umbagog National Wildlife Refuge, Coos County, NH, and Oxford County, ME

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability: Final comprehensive conservation plan and environmental impact statement.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability for review of our final comprehensive conservation plan (CCP) and environmental impact statement (EIS) for Lake Umbagog National Wildlife Refuge (NWR). This document describes how we propose to manage the refuge for the next 15 years.

DATES: We will sign a record of decision no sooner than 30 days after the publication of this notice.

ADDRESSES: You may view or obtain copies of the final CCP/EIS by any of the following methods. You may request a print copy or CD–ROM.

Agency Web Site: Download a copy of the document(s) at *http://library.fws.gov/ccps.htm.*

E-mail: northeastplanning@fws.gov. Include ''Lake Umbagog Final CCP/EIS'' in the subject line of your message.

Mail: P.O. Box 240, Errol, NH 03579–0240.

In-Person Viewing or Pickup: Call 603–482–3415, ext. 20, to make an appointment during regular business hours at Route 16 North, Errol, NH.

FOR FURTHER INFORMATION CONTACT: For answers to questions about the refuge, contact Paul Casey, Refuge Manager, 603–482–3415, ext. 20, e-mail: *paul_casey@fws.gov* or, for questions about the planning process, contact Nancy McGarigal, Natural Resource Planner, 413–253–8562, e-mail: *northeastplanning@fws.gov.* Please remember to put ''Lake Umbagog NWR Final CCP/EIS'' in the subject line of your message.

SUPPLEMENTARY INFORMATION:

Introduction

Our publishing this notice of availability facilitates the CCP process for Lake Umbagog NWR that we started by publishing a notice of intent in the **Federal Register** (67 FR 136; July 16, 2002). For more about the process, see that notice. We released the draft CCP/EIS to the public and requested your comments in a notice of availability in the **Federal Register** (72 FR 129; July 6, 2007).

We are announcing the availability of the final CCP/EIS for Lake Umbagog NWR, and our preferred actions for managing it, in accordance with the National Environmental Policy Act (NEPA) (40 CFR 1506.6(b)). The document contains a thorough analysis of impacts on the human environment. Our next planning step will be to complete a Record of Decision no sooner than 30 days after publication of this notice (40 CFR 1506.10(b)(2)).

The CCP will guide us in managing and administering the refuge for the next 15 years. We propose that alternative B, the Service-preferred alternative, serve as the foundation for the final, stand-alone CCP. We highlight the modifications we made to alternative B between the draft and final CCP/EIS in ''Comments,'' below.

Our first purchase of land for the refuge established it in 1992. Its purposes are to provide long-term protection for unique wetlands, federal- and state-listed threatened or endangered species, migratory birds of conservation concern, and regionally significant concentrations of wildlife.

This 21,650-acre refuge lies in Coos County, New Hampshire, and Oxford County, Maine. It contains widely diverse types of upland and wetland habitats around the 8,500-acre Umbagog Lake. Since establishing the refuge, we have focused primarily on conserving land within its approved boundary, monitoring the occupancy and productivity of its common loon, bald eagle, and osprey nesting sites and protecting them from human disturbance, conducting baseline biological inventories, and providing public opportunities for wildlife-dependent recreation.

Background

The CCP Process

The National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd–668ee; Improvement Act), which amends the National Wildlife Refuge System Administration Act of 1966, requires us to develop a CCP for each national wildlife refuge. The purpose for developing CCPs is to provide refuge managers with 15-year plans for achieving refuge purposes, contributing toward the mission of the National Wildlife Refuge System (NWRS), and conforming to sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public: Hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least once every 15 years, also in accordance with the Improvement Act.

CCP Alternatives

Our draft CCP/EIS (72 FR 129) and this final CCP/EIS fully analyze three alternatives for the future management of the refuge. During the planning process, we identified and addressed 18 major issues generated by several sources: the public, state or federal agencies, other Service programs, and our planning team. Both the draft and final plans identify alternative B as the Service-preferred alternative.

Comments

We solicited comments on the draft CCP/EIS for Lake Umbagog refuge for a 45-day period starting on July 6, 2007 (72 FR 129). In response to requests for additional time, we extended that comment period another 32 days, until September 21, 2007. We held five public hearings and two information sessions during that time, and received 14,269 responses, both oral and written. We evaluated all of the written and electronic correspondence and oral testimony we received, and responded to them in final CCP/EIS appendix O, ''Summary of, and the Service's