

compounding that should be primarily overseen by the States and higher risk non-traditional pharmacy compounding that would require compliance with Federal standards. In addition, there are open questions about whether, and to what degree States should enforce Federal standards, what that oversight should look like, and the appropriate level of communication and coordination required to make the system of State and Federal oversight seamless and effective.

FDA recognizes that the States play a critical role in the oversight of traditional pharmacy compounding, which can include compounding a customized medication in response to a prescription by a licensed practitioner based on the identified medical need of a particular patient for the compounded product. However, a category of “non-traditional” compounding has evolved in the last decade that FDA believes requires additional oversight. The Agency is working with Congress to consider new authorities regarding “non-traditional” compounding pharmacies. In recognition of the States’ role, FDA has also reached out to its State partners by inviting representatives from all 50 States to an intergovernmental meeting.

## II. Questions for Comment

The intergovernmental meeting will be an opportunity for the State officials to discuss a variety of issues regarding their views on the role of the FDA and the States in the oversight of compounding including:

- Given existing authorities and resources, are the States currently able to provide the needed oversight of pharmacy compounding and consumer protection?
- What should the Federal role be in regulating higher risk pharmacy compounding such as compounding high-volumes of drugs for interstate distribution? Is there a way to re-balance Federal and State participation in the regulation of pharmacy compounding that would better protect the public health? What strategies should be developed to further strengthen Federal/State communications?
- Do you see a role for the States in enforcing a Federal standard for “non-traditional” compounding? If so, what role? What factors would affect a decision by your State to take on such responsibility?

The public meeting announced in this document will be held after the intergovernmental meeting described above. FDA is holding this public meeting to share the results of the intergovernmental meeting with

interested stakeholders. At the public meeting, FDA representatives and participants from the intergovernmental meeting will summarize the results of the intergovernmental meeting.

## III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. The Fungal Meningitis Outbreak: Could It Have Been Prevented? Statement of Margaret A. Hamburg, M.D., before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations (<http://www.fda.gov/NewsEvents/Testimony/ucm327664.htm>), November 14, 2012.

2. Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak: Margaret A. Hamburg, M.D., before the Senate Committee on Health, Education, Labor, and Pensions (<http://www.fda.gov/NewsEvents/Testimony/ucm327667.htm>), November 15, 2012.

Dated: November 21, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA–2012–0027; OMB No. 1660–0054]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request, Assistance to Firefighters Grant Program-Grant Application Supplemental Information

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**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.

There has been a change in the respondents, estimated burden, and estimated total annual burden hours from previous 30 day Notice. This change is a result of including the time, effort, and resources to collect information to be used by respondents as well as the significant decline in respondents expected.

**DATES:** Comments must be submitted on or before December 28, 2012.

**ADDRESSES:** 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 the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to [oir.submission@omb.eop.gov](mailto:oir.submission@omb.eop.gov) or faxed to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598–3005, facsimile number (202) 646–3347, or email address [FEMA-Information-Collections-Management@dhs.gov](mailto:FEMA-Information-Collections-Management@dhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Collection of Information

*Title:* Assistance to Firefighters Grant Program-Grant Application Supplemental Information.

*Type of Information Collection:* Revision of a currently approved information collection.

*OMB Number:* OMB No. 1660–0054.

*FEMA Forms:* FEMA Form 080–2, AFG Application (General Questions and Narrative); FEMA Form 080–2a, Activity Specific Questions for AFG Vehicle Applicants; F FEMA Form 080–2b, Activity Specific Questions for AFG Operations and Safety Applications; FEMA Form 080–3, Activity Specific Questions for Fire Prevention and Safety Applicants; FEMA Form 080–3a, Fire Prevention and Safety; and FEMA Form 080–3b, Research and Development

*Abstract:* The FEMA forms for this collection are used to objectively evaluate each of the anticipated applicants to determine which applicants’ submission in each of the AFG activities are close to the established program priorities. FEMA also uses the information to determine eligibility and whether the proposed use

of funds meets the requirements and intent of AFG legislation.

*Affected Public:* State, Local or Tribal Government, and Not-for-profit institutions.

*Estimated Number of Respondents:* 28,010.

*Estimated Total Annual Burden*

*Hours:* 201,130 hours.

*Frequency of Response:* One Time.

Dated: November 21, 2012.

**Charlene D. Myrthil,**

*Director, Records Management Division,  
Mission Support Bureau, Federal Emergency  
Management Agency, Department of  
Homeland Security.*

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R1-R-2012-N114; 1265-0000-10137-S3]

#### **Dungeness National Wildlife Refuge, Clallam County, WA; Comprehensive Conservation Plan and Environmental Assessment**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft comprehensive conservation plan and environmental assessment (Draft CCP/EA) for Dungeness National Wildlife Refuge (refuge or NWR) for public review and comment. The Draft CCP/EA describes our proposal for managing the refuge for the 15 years following approval of the final CCP. Implementing the CCP is subject to the availability of funding and any other compliance regulations.

**DATES:** To ensure consideration, please send your written comments by December 28, 2012.

**ADDRESSES:** You may submit comments or requests for copies or more information by any of the following methods. You may request hard copies or a CD-ROM of the documents.

*Email:*

*FW1PlanningComments@fws.gov.*

Include "Dungeness NWR draft CCP" in the subject line of the message.

*Fax:* Attn: Project Leader, (360) 457-9778.

*U.S. Mail:* Washington Maritime National Wildlife Refuge Complex, 715 Holgerson Road, Sequim, WA 98382.

*Web site:* <http://www.fws.gov/pacific/planning/main/docs/wa/docsdungeness.htm>.

*In-Person Drop-off, Viewing, or Pickup:* Call (360) 457-8451 to make an appointment (necessary for viewing/pickup only) during regular business hours at the above address. For more information on locations for viewing or obtaining documents, see "Public Availability of Documents" under **SUPPLEMENTARY INFORMATION.**

#### **FOR FURTHER INFORMATION CONTACT:**

Kevin Ryan, Project Leader, Washington Maritime National Wildlife Refuge Complex, 715 Holgerson Road, Sequim, WA 98382; phone (360) 457-8451 and fax (360) 457-9778.

#### **SUPPLEMENTARY INFORMATION:**

##### **Introduction**

With this notice, we continue the CCP process for Dungeness NWR in Clallam County, Washington. We started this process through a notice in the **Federal Register** (76 FR 61378; October 4, 2011). For more information about the history of the refuge, see that notice.

##### **Background**

###### *The CCP Process*

The National Wildlife Refuge System Administration Act of 1966, 16 U.S.C. 668dd-668ee (Refuge Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, 111 Stat. 1254, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System (NWRS), consistent with sound principles of fish and wildlife management, conservation, legal mandates, the National Environmental Policy Act (NEPA), and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify compatible wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Refuge Administration Act.

###### *Public Outreach*

We began public outreach by publishing a notice of intent in the **Federal Register** (76 FR 61378; October 4, 2011) announcing our intent to complete a CCP and EA for the refuge and inviting public comments. In October 2011, we distributed Planning Update 1, which included background

information on the refuge; refuge purposes; preliminary issues, vision, and goals; and a request for public comments. Some scoping comments we received were about broad or long-range issues, while others suggested very specific or detailed strategies that could be used to achieve biological or public use objectives. The comments were categorized into eight general categories: Threats to refuge resources; wildlife and habitat management; wildlife-dependent public use; non-wildlife-dependent public use; law enforcement; cultural resources; land acquisition; and refuge administration.

We reviewed and evaluated the potential issues, management concerns, and opportunities that we, our partners, and the public identified during scoping. We used this information to define the major issues to be addressed in the CCP/EA. Preliminary draft alternatives were then developed to address these issues and meet the goals and objectives of the refuge. In January 2012, we distributed Planning Update 2, which included a summary of the scoping comments we received, a summary of our preliminary draft alternatives, notice of public open house meetings, and information on how and where to comment. On January 19 and February 2, 2012, we held a total of four public open house meetings in Sequim, Washington, to meet the public, present our preliminary draft alternatives, and solicit comments. The meetings were announced through local media outlets, on the refuge's Web site, and in Planning Update 2. Comments we received have been considered and evaluated, with many incorporated into the various alternatives addressed in the draft CCP/EA.

#### **Draft CCP/EA Alternatives We Are Considering**

During the public scoping process with which we started work on this draft CCP, we, other governmental partners, Tribes, and the public raised several issues, which the draft CCP addresses. A full description of each alternative is in the EA. To address these issues, we developed and evaluated the following alternatives, briefly summarized below.

##### *Common to All Alternatives*

The New Dungeness Light Station, within the approved refuge boundary, is due to be excised by the U.S. Coast Guard (USCG). Under all alternatives, the Service would work with the USCG to bring the light station property into the NWRS either through interagency cooperative management agreement or property transfer. Subsequently, the