

performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before December 2, 2009.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Edward Chambers, Procurement Analyst, Contract Policy Branch, GSA (202) 501-3221 or e-mail Edward.chambers@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

Firms performing under Federal cost-reimbursement contracts are required to notify the contracting officer in writing whenever they have reason to believe—

(1) The costs the contractors expect to incur under the contracts in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost of the contracts; or

(2) The total cost for the performance of the contracts will be greater or substantially less than estimated. As a part of the notification, the contractors must provide a revised estimate of total cost.

B. Annual Reporting Burden

Respondents: 53,456.

Responses per Respondent: 1.

Annual Responses: 53,456.

Hours per Response: .5.

Total Burden Hours: 26,728.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0074, Contract Funding—Limitation of Costs/Funds, in all correspondence.

Dated: October 23, 2009.

Al Matera,

Director, Acquisition Policy Division.

[FR Doc. E9-26353 Filed 10-30-09; 8:45 am]

BILLING CODE 6820-EP-P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0053]

Federal Acquisition Regulation; Submission for OMB Review; Permits, Authorities, or Franchises Certification

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding a reinstatement of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning permits, authorities, or franchises certification. A request for public comments was published in the **Federal Register** at 74 FR 28497 on June 16, 2009.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before December 2, 2009.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Jeritta Parnell, Procurement Analyst, Contract Policy Branch, GSA (202) 501-4082 or e-mail Jeritta.Parnell@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

This certification and copies of authorizations are needed to determine that the offeror has obtained all authorizations, permits, etc., required in connection with transporting the material involved. The contracting officer reviews the certification and any documents requested to ensure that the offeror has complied with all regulatory requirements and has obtained any permits, licenses, etc., that are needed.

B. Annual Reporting Burden

Respondents: 1,106.

Responses per Respondent: 3.

Annual Responses: 3,318.

Hours per Response: .094.

Total Burden Hours: 312.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0053, Permits, Authorities, or Franchises Certification, in all correspondence.

Dated: October 23, 2009.

Al Matera,

Director, Acquisition Policy Division.

[FR Doc. E9-26348 Filed 10-30-09; 8:45 am]

BILLING CODE 6820-EP-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declaration Regarding Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 360bbb-3(b)(4). On April 26, 2009, the then Acting Secretary of HHS determined that a public health emergency exists nationwide involving Swine Influenza A (now known as 2009-H1N1 Influenza A, or 2009-H1N1 influenza) that affects or has significant potential to affect

national security. On July 24 and October 1, 2009 the Secretary renewed that determination of a public health emergency. On the basis of this determination, on October 20, 2009 the Secretary declared an emergency justifying the authorization of emergency use of the antiviral product peramivir accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs (Commissioner) under 21 U.S.C. 360bbb-3(a). The Secretary also specified that this declaration is a declaration of emergency as defined in the Declaration under the Public Readiness and Emergency Preparedness (PREP) Act for Influenza Antiviral peramivir.

DATES: The declaration of an emergency justifying the authorization of emergency use of the antiviral product peramivir is effective October 20, 2009.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FFDCA, the Commissioner, acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product, or an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare an emergency justifying the authorization based on one of three determinations: A determination of a domestic emergency, or a significant potential for a domestic emergency, by the Secretary of Homeland Security; a determination of a military emergency, or a significant potential for a military emergency, by the Secretary of Defense; or a determination of a public health emergency by the Secretary of HHS. See 21 U.S.C. 360bbb-3(b)(1). In the case of a determination by the Secretary of HHS (as was made here), the Secretary must determine that a public health emergency exists under section 319 of the Public Health Service (PHS) Act that affects, or has a significant potential to affect, national security, and that involves a specified biological,

chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. Based on such a determination, the Secretary of HHS may then declare an emergency that justifies the EUA, at which point the Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FFDCA are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the Food and Drug Administration (FDA) issue an EUA for the antiviral product peramivir accompanied by emergency use information. The determination of a public health emergency by the Acting Secretary of HHS, renewal of that determination by the Secretary of HHS, and the declarations of an emergency by the Secretary of HHS based on that determination, as described below, enable the Commissioner to issue an EUA for certain antiviral products for emergency use under section 564(a) of the FFDCA, 21 U.S.C. 360bbb-3(a).

II. Determination of the Acting Secretary of Health and Human Services and Renewal of the Determination by the Secretary of Health and Human Services

On April 26, 2009, pursuant to section 564(b)(1)(C) of the FFDCA, 21 U.S.C. 360bbb-3(b)(1)(A), and section 319 of the PHS Act, 42 U.S.C. 247d, the Acting Secretary of HHS determined, as a consequence of confirmed cases of Swine Influenza A (now called "2009-H1N1 influenza") in California, Texas, Kansas, and New York, and after consultation with public health officials as necessary, that a public health emergency exists nationwide involving 2009-H1N1 influenza that affects or has significant potential to affect national security.

On July 24 and October 1, 2009 pursuant to section 564(b)(1)(C) of the FFDCA, 21 U.S.C. 360bbb-3(b)(1)(A), and section 319 of the PHS Act, 42 U.S.C. 247d, because the 2009-H1N1 flu outbreak remains a worldwide public health threat and because the Department should use all available tools to ensure that we are prepared, and after consultation with public health officials as necessary, the Secretary renewed the April 26, 2009 determination by then Acting Secretary Charles E. Johnson that a public health emergency exists nationwide involving Swine Influenza A (now called "2009-H1N1 influenza") that affects or has significant potential to affect national security.

III. Declaration of the Secretary of Health and Human Services

On October 20, 2009, on the basis of my renewal on July 24 and October 1, 2009, of the April 26, 2009 determination by Acting Secretary Charles E. Johnson that a public health emergency exists involving Swine Influenza A (now called "2009-H1N1 influenza") that affects or has significant potential to affect national security, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b), I, Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, hereby declare an emergency justifying the authorization of the emergency use of the antiviral peramivir, accompanied by emergency use information, subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). This declaration is a declaration of emergency, as defined in the Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Antiviral peramivir, which was signed September 25, 2009, and any amendments thereto.

Notice of the authorizations issued by the FDA Commissioner under 21 U.S.C. 360bbb-3 is provided elsewhere in this **Federal Register**.

Dated: October 23, 2009.

Kathleen Sebelius,
Secretary.

[FR Doc. E9-26294 Filed 10-30-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: OCSE-75 Tribal Child Support Enforcement Program Annual Data Report.

OMB No.: 0970-0320.

Description: The data collected by form OCSE-75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title IV-D of the Social Security Act are required to report program status and accomplishments and submit the OCSE-75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each Tribe.