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]

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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.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–75	36	1	60	2,160

Estimated Total Annual Burden Hours: 2,160.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 28, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–26315 Filed 10–30–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Public Health Notification Readership Survey (Formerly Known as ''Safety Alert/ Public Health Advisory Readership Survey'')

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 2, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0341. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Public Health Notification Readership Survey (formerly known as Safety Alert/Public Health Advisory Readership Survey) (PHS Act, Section 1701(a)(4)); (OMB Control Number 0910–0341—Extension)

Section 705(b) of the Federal Food Drug and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH), communicates these risks to user communities through two publications: (1) The Public Health Notification (PHN) and (2) the Preliminary Public Health Notification (PPHN). The PHN is published when CDRH has information or a message to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type, and that information may not be readily available to the affected target audience in the health care community. CDRH can make recommendations that will help the health care practitioner mitigate or avoid the risk.

The PPHN is also published when CDRH has information to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type. However, two additional conditions exist that make the use of this type of notification preferable: (1) CDRH's understanding of the problem, its cause(s), and the scope of the risk that is still evolving, so that in order to minimize the risk, the center believes that health care practitioners needs the information they can provide, however incomplete, as soon as possible and (2) the problem is actively being investigated by the center, private industry, another agency or some other reliable entity, so that the center expects to be able to update the PPHN when definitive new information becomes available. Notifications are sent to organizations affected by risks discussed in the notification, such as hospitals, nursing homes, hospices, home health care agencies, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to