to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

Proposed Project: Application for Waiver of the 2-Year Foreign Residence Requirement of the Exchange Visitor Waiver Program, OMB No. 0990–0001—Extension, Office of the Secretary, Office of Global Health Affairs.

Abstract: The Office of Global Health Affairs is requesting an extension on a previous approved collection OMB #0990–0001—Application for Waiver of the 2-Year Foreign Residence Requirement of the Exchange Visitor Waiver Program. This form and supplementary information sheets is used by this Department to make a determination, in accordance with its published regulations, as to whether or not to request from the Department of State, a waiver of the two-year foreign residence requirement for applicants in the United States on a J–1 visa. The type of respondent is voluntary; the affected public is business for profit, not-for profit institutions, Federal Government, State, Local or Tribal Government

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
HHS–426	Research Applications	150	1	10	1500
HHS–426	Clinical Care Research	50	1	10	500
Total					2000

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2010–7445 Filed 4–1–10; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declarations Regarding Emergency Use of Certain In vitro Diagnostic, Antiviral, and Personal Respiratory Products 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 the basis of this determination, on April 26 and April 27, 2009, the then Acting Secretary declared emergencies justifying the authorization of emergency use of certain in vitro diagnostic, antiviral, and personal respiratory protection products 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 then Acting Secretary also specified that these declarations are declarations of emergency as defined by former Secretary Michael O. Leavitt in the October 10, 2008 Declaration under the Public Readiness and Emergency Preparedness (PREP) Act for Influenza Antivirals Oseltamivir Phosphate and Zanamavir, as amended, and the December 17, 2008 Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices. The Secretary renewed the then Acting Secretary's determination that a public health emergency exists nationwide involving Swine Influenza A (now known as 2009 H1N1 Influenza) on July 24, October 1, and December 28, 2009, and March 26, 2010. Also on March 26, 2010, the Secretary renewed the then Acting Secretary's declarations of emergency justifying the authorization of emergency use of certain in vitro diagnostic, antiviral, and personal respiratory protection products 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).

DATES: The declaration of an emergency justifying the authorization of emergency use of certain in vitro diagnostic products is renewed effective March 26, 2010. The declaration of an emergency justifying the authorization of certain antiviral products is renewed effective March 26, 2010. The declaration of an emergency justifying the authorization of emergency use of certain respiratory protection products is renewed effective March 26, 2010.

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 EUAs for certain in vitro diagnostic, antiviral, and personal respiratory protection products accompanied by emergency use information. The determination of a public health emergency by the then Acting Secretary and declarations of an emergency by the then Acting Secretary based on that determination, published at 74 FR 38628 (August 4, 2009), enabled the then Acting Commissioner to issue EUAs for certain in vitro diagnostic, antiviral, and personal respiratory protection products, published at 74 FR 38636 (August 4, 2009), 71 FR 38641 (August 4, 2009) and 71 FR 38645 (August 4, 2009). The CDC has requested that the FDA continue these EUAs to support continued surveillance of 2009 H1N1 influenza through use of certain in vitro diagnostic products. Continuation of the EUAs is also important to support continued availability and disposition of certain antiviral products to treat individuals who are ill following exposure to 2009 H1N1 influenza and to support continued availability and disposition of certain personal respiratory products to help reduce wearer exposure to airborne viruses during the 2009 H1N1 influenza emergency. The renewed determination of a public health emergency by the Secretary of HHS and the renewed declarations of an emergency by the Secretary of HHS based on that determination justify the authorization of the emergency use of the above products.

In this public health emergency involving 2009 H1N1 influenza, time continues to be of the essence in detecting, preventing, and treating illness and death by getting in vitro diagnostic, antiviral, and personal respiratory protection products, accompanied by emergency use information, to the general public, laboratories, and public health and health care professionals. By continuing to distribute certain in vitro diagnostic products accompanied by emergency use information, public health and health care professionals can ensure that any continued spread of the 2009 H1N1 influenza is quickly and accurately detected. By dispensing certain personal respiratory products accompanied by emergency use information, the appropriate State and/or public health authority(ies) can ensure that the products are provided quickly, as appropriate, to help reduce wearer exposure to airborne germs. By dispensing certain antiviral products accompanied by emergency use information, public health and medical professionals and the authorities having jurisdiction to respond to the emergency in each locality can ensure that the products are provided quickly, as appropriate, to treat those who may have been exposed or are ill.

This is one part of the Federal Government's strategy to encourage continued preparedness at all levels of government to enable the nation to respond effectively in response to this public health emergency.

II. Determination of the Secretary of Health and Human Services

On March 26, 2010, 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. The Secretary renewed the Acting Secretary's determination, after consultation with public health officials as necessary and pursuant to authority under section 319 of the Public Health Service Act 42 U.S.C. 247d, because the 2009 H1N1 Influenza outbreak remains a worldwide public health threat. The Secretary previously renewed the Acting Secretary's determination on July 24, 2009, October 1, 2009, and December 28, 2009.

III. Declarations of the Secretary of Health and Human Services

On March 26, 2010, the Secretary renewed the April 26, 2009 declaration by then Acting Secretary Charles E. Johnson of an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for detection of Swine Influenza A (now called 2009 H1N1 Influenza) accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). This renewal was made on the basis of the April 26, 2009 determination by then Acting Secretary Charles E. Johnson, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, 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, a determination which was renewed on July 24, 2009, October 1, 2009, December 28, 2009 and March 26, 2010 because 2009 H1N1 flu outbreak remains a public health threat and the Department should use all available tools to ensure that the nation is prepared. The renewal of this April 26, 2009 declaration was made pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b). In renewing the declaration, the Secretary further specified that the declaration is a declaration of emergency, as defined in the December 17, 2008 Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 FR 78362 (December 22, 2008).

Also on March 26, 2010, the Secretary renewed the April 26, 2010 declaration by then Acting Secretary Charles E. Johnson of an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of Antivirals Oseltamivir Phosphate and Zanamivir accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). This renewal was made on the basis of the April 26, 2009 determination by then Acting Secretary Charles E. Johnson, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, 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, a determination which was renewed on July 24, 2009, October 1, 2009, December 28, 2009, and March 26, 2010 because 2009 H1N1 flu outbreak remains a public health threat and the Department should use all available tools to ensure the nation is prepared. The renewal of this April 26, 2009 declaration was made pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b). In renewing the declaration, the Secretary further specified that the declaration is a declaration of emergency, as defined in the October 10, 2008 Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Antivirals Oseltamivir Phosphate and Zanamivir, 73 FR 61861 (October 17, 2008), as amended at 74 FR 2913 (April 26, 2009).

Also on March 26, 2010, the Secretary renewed the April 27, 2009 declaration by then Acting Secretary Charles E. Johnson of an emergency justifying the authorization of the emergency use of

certain personal respiratory protection devices, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C 360bbb–3(a). This renewal was made on the basis of the April 26, 2009 determination by then Acting Secretary Charles E. Johnson, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, 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, a determination which was renewed on July 24, 2009, October 1, 2009, December 28, 2009 and March 26, 2010 because 2009 H1N1 flu outbreak remains a public health threat and the Department should use all available tools to ensure that the nation is prepared. The renewal of this April 27, 2009 declaration was made pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb–3(b). In renewing this declaration, the Secretary further specified that the declaration is a declaration of emergency, as defined in the December 17, 2008 Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 FR 78362 (December 22, 2008).

Dated: March 26, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–7529 Filed 4–1–10; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

Proposed Project: Multiplier Surveys—NEW

While all SAMHSA programming is intended to support the SAMHSA vision of a life in the community for everyone, and its strategic goals of accountability, capacity, and effectiveness, there has been little systematic investigation of the long-range impact of different categories of discretionary programs. The Multiplier Surveys will inform SAMHSA policy and budget development by determining which types of investments are most appropriate for achieving different policy objectives, including sustainability of the program or its intended outcomes after Federal funding ends. It also seeks to determine which program types or factors are best at achieving certain objectives after the conclusion of Federal funding, such as capacity improvement, system change, sustainability and influence on other programs. Findings will be used to make recommendations to SAMHSA management to better inform policy and budget development and to determine which types of investments are most appropriate for achieving different policy objectives.

To achieve the goals of the Multiplier Surveys four programs have been chosen from each of SAMHSA's three Centers. Four Project Directors from each of the 12 programs (48 respondents in all), whose Federal funding ended no later than September 30, 2008 will be interviewed by telephone to determine how the project was sustained after Federal funding ended and what factors contributed to its sustainability.

In addition, all grantees from each of the 12 selected programs meeting inclusion criteria will be invited via e-mail to complete a short on-line survey about their project and how/if it was sustained after Federal funding ended. A 20 percent response rate or about 100 respondents to the on-line survey is expected.

The estimated response burden is as follows:

Information source	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
Project Director	48	1	48	1.25	60
Web-based Survey	100	1	100	.75	75
Total	148	.....	148	.....	135