DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Comment Request

Title: Innovative Strategies for Increasing Self-Sufficiency: Follow-Up Data Collections.

OMB No.: 0970–0397.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Innovative Strategies for Increasing Self-Sufficiency (ISIS) evaluation. ISIS is an evaluation of 9 promising career pathways strategies to promote education, employment, and self-sufficiency. The major goal of ISIS is to increase the empirical knowledge about the effectiveness of programs for low-income individuals and families to achieve educational credentials, attain employment and advance to positions that enable self-sufficiency.

ISIS is one project within the broader portfolio of research that OPRE is utilizing to assess the success of the career pathways programs and models. In addition to ISIS, this strategy includes a multi-pronged research and evaluation approach for the Health Profession Opportunity Grants (HPOG) Program to better understand and assess the activities conducted and their results. In order to maximize learning across this portfolio, survey development for the HPOG and ISIS baseline and follow up surveys is being coordinated, and the majority of the data elements collected in these surveys are similar.

Two data collection efforts have been approved for ISIS, including one for baseline data collection (approved November 2011), a second for data collection activities to document program implementation, data collection activities for an initial follow-up survey of participants to be administered approximately 15 months after random assignment, and data collection through in-depth interviews for a small sample of study participants (approved August 2013). Additionally, three related data collection efforts for HPOG research were approved by OMB under OMB #0970–0394. These include approval of a Performance Reporting System (PRS) (approved September 2011), for collection of additional baseline data for the HPOG-Impact study (approved October 2012), and for collection of data for the National Implementation Evaluation (approved August 2013). Additionally, a new request is being submitted at the same time as this request.

This **Federal Register** Notice provides the opportunity to comment on a proposed new information collection activity for ISIS—a second follow-up survey for ISIS participants approximately 36 months after program enrollment. The purpose of the survey is to follow-up with study participants to document their education and training experiences, employment experiences, and parenting practices and child outcomes for participants with children.

Data collection activities to submit in a future information collection request include a third follow-up survey for ISIS study participants approximately 60 months after study enrollment.

Previously approved collection activities under 0970–0397 will continue under this new request, including additional data collection using the following previously approved instruments: The Basic Information Form; the Self-Administered Questionnaire; 15-Month Follow-Up Survey; 15-Month Follow-Up Survey Tracking Letters; Study Participant In-depth Interview Guide; and Study Participant Check-in Call the estimated number of study participants for the 15-Month Survey and in-depth interviews is reduced from the previous OMB submission. Total sample size targets were reduced at a number of ISIS program sites to reflect actual study enrollment experiences. The number of in-depth interviews projected was also reduced to incorporate experiences to date recruiting participants.

Respondents: Individuals enrolled in the ISIS study.

ANNUAL BURDEN ESTIMATES

[This information collection request is for a three-year period]

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Previously Approved Instruments					
Baseline data collection: Basic Information Form	24	8	1	.25	2
Baseline data collection: Self-administered Questionnaire	24	8	1	.33	3
15 Month Follow-up Survey	2,900	967	1	0.833	805
15-Month Follow-up Survey Tracking Letters	1,782	594	3	0.083	148
Study Participant In-depth Interview Guide	144	48	1	1	48
Study Participant Check-in Call	144	48	1	.16	8
Current Request for Approval					
36-Month Follow-up Survey	7,386	2,462	1	1	2,462
36-Month Follow-up Survey Tracking Letters	7,386	2,462	6	0.083	1,226

Estimated Total Annual Burden Hours: 4,702.

In compliance with the requirements of Section 3506(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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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.

Karl Koerper,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0670]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Novel Influenza A (H7N9) Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the novel influenza A (H7N9) virus (detected in China in 2013). FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Arbor Vita Corporation. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the April 19, 2013, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves the novel influenza A (H7N9) virus. On the basis of such determination, the Secretary of HHS also declared on April 19, 2013, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the novel influenza A (H7N9) virus subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of April 25, 2014.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Office of Counterterrorism and Emerging Threats, and Acting Deputy Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; [1] or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances),

[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Public Law 113–5), the Secretary of HHS may make a determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary of HHS is no longer required to make a determination of a public health emergency under section 319 of the PHS Act (42 U.S.C. 247d) to support a determination made under section 564 of the FD&C Act.