NOTIFICATION PROCEDURE:

Individuals wishing to inquire if the system contains information about them should contact the system manager at the above address.

CONTESTING RECORD PROCEDURES:

Rules for contesting the content of a record and appealing a decision are contained in 41 CFR 105–64.

RECORD SOURCES CATEGORIES:

The sources for information in the system are the individuals about whom the records are maintained, the supervisors of those individuals, existing GSA systems, sponsoring agency, former sponsoring agency, other Federal agencies, contract employer, former employer, and the U.S. Office of Personnel Management (OPM).

[FR Doc. 2014–19079 Filed 8–11–14; 8:45 am]

BILLING CODE 6820–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, 21 U.S.C. 360bbb–3. On September 22, 2006, then Secretary of Homeland Security, Michael Chertoff, determined pursuant to section 319F–2 of the Public Health Service Act, 42 U.S.C. 247d–6b, that the Ebola virus presents a material threat against the United States population sufficient to affect national security.

On the basis of this determination, on August 4, 2014 the Secretary declared that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration are effective August 4, 2014.

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 FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) 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 that circumstances exist justifying the authorization based on one of four determinations: (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 (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) 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 United States military forces of attack with a CBRN agent or agents; or (4) a determination by the Secretary 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 United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The Department of Defense requested that the FDA issue an EUA for *in vitro* diagnostics for detection of Ebola virus to allow the Defense Department to take preparedness and response measures based on information currently available about the Ebola virus in Western Africa. The material threat determination by the Secretary of Homeland Security, and the declaration that circumstances exist justifying emergency use of *in vitro* diagnostics for detection of Ebola virus by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for certain *in vitro* diagnostics for emergency use under section 564 of the FD&C Act.

[1] 42 U.S.C. 247d–6b, which states: ''[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.''

II. Material Threat Determination by the Secretary of Homeland Security

On September 22, 2006, then Secretary of Homeland Security, Michael Chertoff, determined pursuant to section 319F–2 of the Public Health Service Act, 42 U.S.C. 247d–6b, that the Ebola virus presents a material threat against the United States population sufficient to affect national security.

III. Declaration of the Secretary of Health and Human Services

On August 4, 2014, on the basis of the Secretary of Homeland Security's determination that the Ebola virus presents a material threat against the United States population sufficient to affect national security, I declared that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: August 5, 2014.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2014–19026 Filed 8–11–14; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human

Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting September 9–10, 2014. The meeting is open to the public. However, pre-registration is required for both public attendance and public comment. Individuals who wish to attend the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac.* Participants may also register by emailing *nvpo@hhs.gov* or by calling 202–690–5566 to provide your name, organization, and email address.

DATES: The meeting will be held on September 9–10, 2014. The meeting times and agenda will be posted on the NVAC Web site at *http://www.hhs.gov/nvpo/nvac* as soon they become available.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast the day of the meeting. For more information, visit *http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/index.html.*

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715–H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690–5566; email: *nvpo@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The topics planned for NVAC discussion will include a presentation on the progress of the development of a National Adult Immunization Plan; plans by the NVPO to conduct a mid-course review of the 2010 National Vaccine Plan; the recent findings of a comprehensive review of vaccine safety; and an overview of vaccine research and development efforts for developing vaccines for use in pregnant women. In addition, the NVAC working group on Vaccine Confidence will present their findings and recommendations for NVAC consideration and discussion. The NVAC also will hear an overview of Canada's efforts to strengthen the Canadian immunization system and an update on our national progress towards the Healthy People 2020 immunization goals. Finally, the NVAC HPV Working Group will provide an update on its progress. The meeting agenda will be posted on the NVAC Web site: *http://www.hhs.gov/nvpo/nvac* prior to the meeting.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/index.html.*

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Individuals who would like to submit written statements should email their comments to the National Vaccine Program Office (*nvpo@hhs.gov*) at least five business days prior to the meeting.

Dated: July 29, 2014.

Bruce Gellin,

Executive Secretary, National Vaccine Advisory Committee, Deputy Assistant Secretary for Health, Director, National Vaccine Program Office.

[FR Doc. 2014–19046 Filed 8–11–14; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Evaluation of the AHRQ Healthcare Horizon Scanning System.'' In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by October 14, 2014.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@ahrq.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

''Evaluation of the AHRQ Healthcare Horizon Scanning System''

The American Recovery and Reinvestment Act (ARRA) appropriated $1.1 billion for comparative effectiveness research (CER), of which $300 million was made available to the Agency for Healthcare Research and Quality (AHRQ). The goal of CER is to improve patient outcomes by providing clinicians and patients the information they need to choose between preventive and diagnostic treatments, and other health care options to identify the options that best fit an individual patient's needs and preferences. The EHC Program was created in response to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

To better inform comparative effectiveness research investments at the EHC Program, AHRQ used some of the ARRA funds to develop a horizon scanning system to identify and monitor emerging health care technologies and innovations. While horizon scanning systems exist in other countries, these systems do not take into account the unique political, regulatory, cultural, and economic context of the U.S. health care system. To meet this need, the AHRQ Healthcare Horizon Scanning System was implemented in November 2010. The AHRQ Healthcare Horizon Scanning System provides a systematic process to identify and monitor target technologies and innovations in health care and to create an inventory of target technologies that have the highest