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