## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### HIT Policy Committee Advisory Meeting; Notice of Meeting

**AGENCY:** Office of the National Coordinator for Health Information Technology, HHS.

**ACTION:** Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

*Name of Committee:* HIT Policy Committee.

*General Function of the Committee:* To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

*Date and Time:* The meeting will be held on October 3, 2012, from 10 a.m. to 3 p.m./ Eastern Time.

*Location:* The Dupont Circle Hotel, 1500 New Hampshire Avenue NW., Washington DC 20036. For up-to-date information, go to the ONC Web site, *http://healthit.hhs.gov*

*Contact Person:* MacKenzie Robertson, Office of the National Coordinator, HHS, 355 E Street SW., Washington, DC 20201, 202–205–8089, Fax: 202–260–1276, email: *mackenzie.robertson@hhs.gov.* Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

*Agenda:* The committee will hear reports from its workgroups and updates from ONC and other Federal agencies. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://healthit.hhs.gov*

*Procedure:* ONC is committed to the orderly conduct of its advisory committee meetings. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before two days prior to the Committee's meeting date. Oral comments from the public will be scheduled in the agenda. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ONC will take written comments after the meeting until close of business on that day.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact MacKenzie Robertson at least seven (7) days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: September 11, 2012.

**MacKenzie Robertson,**

*FACA Program Lead, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 2012–22988 Filed 9–17–12; 8:45 am]

**BILLING CODE 4150–45–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Single Source Cooperative Agreement Award for World Health Organization

**AGENCY:** Department of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR).

**ACTION:** Notification of Single Source Cooperative Agreement Award for World Health Organization for a grant titled: ''Smallpox Research Oversight Activities: WHO Advisory Committee on Variola Virus Research''.

*Statutory Authority:* Sections 301 and 319L of the Public Health Service Act, (42 U.S.C. 241 and 247d–7e).

*Estimated Amount of Award:* $400,000.

*Project Period:* Sept. 30, 2012 to Sept. 29, 2013.

**SUMMARY:** A natural re-emergence of smallpox is not deemed possible, but if it were to occur as a result of a terrorist or deliberate event, it would be a potentially devastating threat to public health worldwide and would constitute a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR) (2005). A case of smallpox detected by a member state requires notification to World Health Organization (WHO) as soon as possible, and any confirmed smallpox case would generate an immediate global public health response.

WHO must rely on fast and reliable laboratory diagnostic capacity worldwide to be able to identify a re-emergence of smallpox, particularly in countries where systemic orthopoxvirus infections such as monkeypox, vaccinia virus infection or cowpox, and other non-pox viral rash illnesses, such as chicken pox, may cause clinical diagnostic confusion.

Over the past 10 years, clinical virology laboratory diagnostics has been evolving and increasingly rely on molecular techniques. This is also true with laboratory diagnoses of poxvirus infections. Precise and consistent identification of orthopoxviruses, in particular variola viruses, is now achievable using such molecular techniques as real-time Polymerase Chain Reaction (unlike earlier techniques that may have relied on direct virus isolation and identification).

WHO must be alerted when there is a potential or actual smallpox infection. Early detection and confirmation of smallpox cannot rely solely on the two WHO Collaborating Centres for smallpox and other poxvirus infections. In order to facilitate and support a prompt and effective response to mitigate the spread of the disease, these two Centres should be supported by a worldwide network of reliable laboratories able to perform PCR and real-time PCR diagnostics enabling initial detection and identification of smallpox events.

Additionally, the U.S. Government supports the development of other medical products, including vaccines and drugs, for use within the U.S. upon verification of a smallpox case. The U.S. government, through the Office of the Assistant Secretary for Preparedness and Response (ASPR), has successfully developed vaccine products, and is actively engaged in the development of several drug candidates for smallpox therapies, which require access to the Variola virus to satisfy regulatory requirements for product approvals.

**Single Source Justification**

WHO is the only eligible applicant; it is the only organization that is allowed by international agreements to address the issues outlined in this proposal. WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats. States Parties to the U.N. have

agreed to international standards on reporting public health incidents of concern under IHR (2005). Additionally, a majority of States Parties have also agreed to specific work-frames for pathogens such as smallpox under the Biological Weapons Convention.

Since May 1999, when the 52nd World Health Assembly (WHA) resolved to postpone the destruction of the Variola virus to allow for essential research (WHA 52.10), WHO has been charged with convening a group of experts to advise on the need for continuing such research, to review proposals for research involving viable Variola virus, to review the progress of such research, and to report to the WHA each year. The need to support the activities described in this project has not changed. In fact, WHO Member States continue to exert pressure for the WHO Secretariat to carry out this work.

The WHO Advisory Committee on Variola Virus Research (ACVVR) was established in 1999 to determine what essential research, if any, must be carried out with live Variola virus. The ACVVR monitored the research progress in order to reach global consensus on the timing for the destruction of existing Variola virus stocks. In 2007, the WHA requested the ACVVR undertake a thorough review of the approved research program with a report presented in 2010. The results were presented at the 64th WHA meeting in May of 2011. The ACVVR continues to serve a critically important function for global public health, and to oversee research requested specifically by the U.S. to complete its national strategic goals. This includes the development of new antiviral agents, safer vaccines, and better diagnostics, thus strengthening our national security.

*Additional Information:* The agency program contact is Richard J. Hatchett, MD, who can be contacted by phone at (202) 260–0150 or via email at *Richard.Hatchett@hhs.gov*.

Dated: September 12, 2012.

**Nicole Lurie,**

*Assistant Secretary for Preparedness and Response.*

[FR Doc. 2012–23017 Filed 9–17–12; 8:45 am]

**BILLING CODE 4150–37–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0386]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 3, 2012 (77 FR 26281). The document announced an opportunity for public comment on the proposed extension of an existing collection of information by the Agency pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and to listing of ingredients in tobacco products under the Family Smoking Prevention and Tobacco Control Act. The document published with incorrect FDA form numbers. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2012–10645 appearing on page 26281 in the **Federal Register** of Thursday, May 3, 2012, the following corrections are made:

1. On page 26282, in the third column, in the first full paragraph, the fifth sentence ''FDA also developed paper forms (Form FDA 3742—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool.'' is corrected to read ''FDA also developed paper forms (Form FDA 3741—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3742—Listing of Ingredients in Tobacco Products) as an alternative submission tool.''

2. On page 26283, in the table, ''Form FDA 3742'' is corrected to read ''Form FDA 3741'' and ''Form FDA 3743'' is corrected to read ''Form FDA 3742''.

Dated: September 12, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–22919 Filed 9–17–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0386]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 3, 2012 (77 FR 46441). The document announced that a proposed collection of information had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The document published with incorrect FDA form numbers. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2012–18975 appearing on page 46441 in the **Federal Register** of Friday, August 3, 2012, the following corrections are made:

1. On page 46442, in the third column, in the first full paragraph, the fifth sentence ''FDA also developed paper forms (Form FDA 3742—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool.'' is corrected to read ''FDA also developed paper forms (Form FDA 3741—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3742—Listing of Ingredients in Tobacco Products) as an alternative submission tool.''