accreditation program expires December 27, 2013.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AOA/HFAP's request for continued CMS approval of its CAH accreditation program. This notice also solicits public comment on whether AOA/HFAP's requirements meet or exceed the Medicare conditions of participation for CAHs.

III. Evaluation of Deeming Authority Request

AOA/HFAP submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its CAH accreditation program. This application was determined to be complete on May 31, 2013. Under section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of AOA/HFAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AOA/HFAP's standards for CAHs as compared with CMS' CAH conditions of participation.
- AOA/HFAP's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of AOA/HFAP's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ AOA/HFAP's processes and procedures for monitoring a CAH found out of compliance with AOA/HFAP's program requirements. These monitoring procedures are used only when AOA/HFAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.7(d).

++ AOA/HFAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ AOA/HFAP's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AOA/HFAP's staff and other resources, and its financial viability.

++ AOA/HFAP's capacity to adequately fund required surveys.

++ AOA/HFAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AOA/HFAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–15175 Filed 6–24–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0651]

Authorization of Emergency Use of an In Vitro Diagnostic for Detection of the Novel Avian 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 avian influenza A(H7N9) virus. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic (FD&C) Act, as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the 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 that involves the novel avian influenza A(H7N9) virus. On the basis of such determination, the Secretary also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the novel avian 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 22, 2013.

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. 32, Rm. 4121, 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4118, 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 (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 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 CDC (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing—(i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as the Secretary of HHS may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Request for an In Vitro Diagnostic for Detection of the Novel Avian Influenza A(H7N9) Virus

On April 19, 2013, under section 564(b)(1)(C) of the FD&C Act (21 U.S.C. 360bbb–3(b)(1)(C)), the Secretary of HHS determined 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 that involves the novel avian influenza A(H7N9) virus. Also on April 19, 2013, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the novel avian influenza A(H7N9) virus, subject to the terms of any authorization issued under section 564 of the FD&C Act. The Secretary also specified that this declaration is a declaration of an emergency with respect to in vitro diagnostics as defined under the Public Readiness and Emergency Preparedness (PREP) Act Declaration for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices signed by then Secretary Michael Leavitt on December 17, 2008 (73 FR 78362). Notice of the determination and the declaration of the Secretary were published in the **Federal**

[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 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 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.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

Register on April 30, 2013 (78 FR 25273). On April 19, 2013, CDC requested, and on April 22, 2013, FDA issued an EUA for the CDC Human Influenza Virus Real-Time RT–PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay subject to the terms of this authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *http://www.regulations.gov.*

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of the novel avian influenza A(H7N9) virus subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 22, 2013

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for the presumptive detection of novel influenza A(H7N9) virus in conjunction with the FDA cleared CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel in real-time RT-PCR (rRT-PCR) assays in patients with signs and symptoms of respiratory infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by public health and other qualified laboratories.

On April 19, 2013, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined 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 United States 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 an agent or agents - in this case, novel influenza A(H7N9) virus.[1] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for the detection of A(H7N9) influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[2]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay (as described in the scope section of this letter (Section II)) for the presumptive detection of A(H7N9) influenza virus in patients with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[2] Memorandum, Determination of a Significant Potential for a Public Health Emergency and Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (April 19, 2013).

I have concluded that the emergency use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for the presumptive detection of A(H7N9) influenza virus in patients with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The A(H7N9) influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay may be effective in diagnosing A(H7N9) influenza virus, and that the known and potential benefits of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay, when used for diagnosing A(H7N9) influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for diagnosing A(H7N9) influenza virus.[3]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for the presumptive detection of A(H7N9) influenza virus in patients with signs and symptoms of respiratory infection.

The Authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay:

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection and differentiation of A(H7N9) influenza viral RNA in upper respiratory tract specimens, such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS) and lower respiratory tract specimens (including bronchoalveolar lavage (BAL), bronchial wash (BW), tracheal aspirate (TA), sputum, and lung tissue from patients with signs and symptoms of respiratory infection. The testing procedure consists of nucleic acid extraction followed by rRT-PCR on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument.

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay includes the following primer and probe sets:

- **INF A:** Primers and probe target the gene encoding the Matrix protein to detect all influenza A strains, but do not detect influenza B strains
- **EuH7**: Primers and probe target the gene encoding the HA protein to detect influenza A/H7 (Eurasian Lineage) virus strains

[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

- **Extraction/Process Control: RP**: Primers and probe detect the human RNase P gene sequence and are used with human clinical specimens to indicate that adequate isolation of nucleic acid resulted from the extraction of the clinical specimen.

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay also includes the following control materials:

- **No Template Control (NTC)**
- **Human Specimen Control (HSC)**
- **Influenza A/H7 (Eurasian Lineage) Positive Control (EuH7PC)**

The above described CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay, when labeled consistently with the labeling authorized by FDA, entitled "CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/ Safety/EmergencySituations/ucm161496.htm), which may be revised with written permission of FDA, is authorized to be distributed to and used by public health and other qualified laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Test Results**

- **Fact Sheet for Patients: Understanding Results from CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay**

As described in section IV below, CDC is also authorized to make available additional information relating to the emergency use of the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay in the specified population, when used for presumptive detection of A(H7N9) influenza virus, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay may be effective in the diagnosis of A(H7N9) influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7

(Eurasian Lineage) Assay, when used to diagnose A(H7N9) influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay described above is authorized to diagnose A(H7N9) influenza virus infection in patients with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

A. CDC will distribute the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay with the authorized labeling, as may be revised with written permission of FDA, only to public health and other qualified laboratories.

B. CDC will provide to the public health and other qualified laboratories the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Fact Sheet for Healthcare Providers and the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Fact Sheet for Patients.

C. CDC will make available on its website the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Fact Sheet for Healthcare Providers and the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Fact Sheet for Patients.

D. CDC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. CDC will ensure that public health and other qualified laboratories using the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate.

F. CDC will track adverse events and report to FDA as required under 21 CFR Part 803.

G. Through a process of inventory control, CDC will maintain records of device usage.

H. CDC will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which CDC becomes aware.

I. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Only CDC may request changes to the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Fact Sheet for Healthcare Providers or the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

Public Health and Other Qualified Laboratories

K. Public health and other qualified laboratories will include with reports of the results of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

L. Public health and other qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the appropriate software.

M. Public health and other qualified laboratories will have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate.

Page 6 – Dr. Frieden, Centers for Disease Control and Prevention

N. Public health and other qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which public health and other qualified laboratories become aware.

CDC, Public Health and Other Qualified Laboratories

O. CDC, public health and other qualified laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15096 Filed 6–24–13; 8:45 am]

BILLING CODE 4160–01–C