(§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded our access to records. Specifically, FSMA expanded our access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that we reasonably believe is likely to be affected in a similar manner. In addition, we can access records if we believe that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. To gain access to these records, our officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner.

On February 23, 2012, we issued an interim final rule in the **Federal Register** (77 FR 10658) (the 2012 IFR) amending § 1.361 to be consistent with the current statutory language in section 414(a) of the FD&C Act, as amended by section 101 of FSMA. In the 2012 IFR, we concluded that the information collection provisions of § 1.361 were exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities (77 FR at 10661). The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361 in table 1.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on our estimate of the number of facilities affected by the final rule entitled ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71650). With regard to records maintenance, we estimate that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, we estimate that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the Agency estimates the number of new firms entering the affected businesses to be 5 percent of 379,493, or 18,975 firms. Thus, we estimate that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. We estimate that approximately the same number of firms (18,975) will exit the affected businesses in any given year, resulting in no growth in the number of total firms reported on line 1 of table 1. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08707 Filed 4–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0306]

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 Quidel 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 February 14, 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. 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, and Acting Deputy Chief Scientist, 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 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), 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 may be prescribed by regulation are satisfied.

No other criteria for 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 Device for Detection of the Novel 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 and that involves the novel 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 influenza A

[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.

(H7N9) virus, subject to the terms of any authorization issued under section 564 of the FD&C Act. The Secretary of HHS 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, December 22, 2008). Notice of the determination and the declaration of the Secretary were published in the **Federal Register** on April 30, 2013 (78 FR 25273). On January 28, 2014, Quidel Corporation requested, and on February 14, 2014, FDA issued, an EUA for the Lyra™ Influenza A Subtype H7N9 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 influenza A (H7N9) virus (detected in China in 2013) 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

February 14, 2014

John Tamerius, Ph.D.
Senior Vice President, Clinical and Regulatory Affairs
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Dear Dr. Tamerius:

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 Lyra™ Influenza A Subtype H7N9 Assay for the presumptive detection of novel influenza A (H7N9) virus (detected in China in 2013) in patients with signs and symptoms of respiratory infection who have positive specimens for influenza A viral RNA that are determined to be un-subtypable, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

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 Lyra™ Influenza A Subtype H7N9 Assay by Clinical Laboratory Improvement Amendments (CLIA) High Complexity Laboratories[3] or foreign laboratories on certain instruments for the presumptive detection of influenza A (H7N9) virus (detected in China in 2013) in certain patients (as described in the scope section of this letter (Section II)), subject to the terms of this 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).
[3] These are laboratories certified under the CLIA of 1988, 42 U.S.C. § 263a, to perform high complexity tests.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Lyra™ Influenza A Subtype H7N9 Assay on the specified instruments for the presumptive detection of influenza A (H7N9) virus (detected in China in 2013) in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The influenza A (H7N9) virus (detected in China in 2013) can cause influenza, a serious or life threatening disease or condition to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Lyra™ Influenza A Subtype H7N9 Assay used on the specified instruments may be effective in diagnosing influenza A (H7N9) virus (detected in China in 2013) in the specified population, and that the known and potential benefits of the Lyra™ Influenza A Subtype H7N9 Assay, when used on the specified instruments for diagnosing influenza A (H7N9) virus (detected in China in 2013) infection in the specified population, 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 Lyra™ Influenza A Subtype H7N9 Assay for diagnosing influenza A (H7N9) virus (detected in China in 2013).[4]

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 Lyra™ Influenza A Subtype H7N9 Assay in conjunction with the bioMerieux NucliSENS® easyMAG® system, followed by rRT-PCR on the Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument, for the presumptive detection of influenza A (H7N9) virus (detected in China in 2013) in patients with signs and symptoms of respiratory infection who have positive specimens for influenza A viral RNA that were determined to be "un-subtypable."

The Authorized Lyra™ Influenza A Subtype H7N9 Assay:

The Lyra™ Influenza A Subtype H7N9 Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection and differentiation of influenza A (H7N9) virus (detected in China in 2013) viral RNA in nasal swabs (NS) and nasopharyngeal swabs (NPS) from patients with signs and symptoms of respiratory infection. It is only authorized for use after a nasal or nasopharyngeal swab specimen has tested positive for influenza A viral RNA by using a FDA-cleared influenza A device, and has been determined to be "un-subtypable" by using FDA-cleared influenza device(s) with subtyping capabilities for all currently circulating influenza A viruses in the United States (i.e., seasonal A/H3 and A/H1 pandemic). The authorized testing consists of nucleic acid extraction on the FDA-cleared bioMerieux NucliSENS® easyMAG® system, followed by rRT-PCR on the FDA-cleared Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument.

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

The Lyra™ Influenza A Subtype H7N9 Assay includes the following reagents:

- **Rehydration Solution**
- **Lyra™ Influenza A Subtype H7N9 Assay Master Mix**

The Lyra™ Influenza A Subtype H7N9 Assay also includes the following control materials:

- **Process Control (PRC)**
- **Avian Influenza A (H7N9) Synthetic DNA Positive Control**

The above described Lyra™ Influenza A Subtype H7N9 Assay, when labeled consistently with the labeling authorized by FDA, entitled "Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 Assay Test Results**

- **Fact Sheet for Patients: Understanding Results from the Lyra™ Influenza A Subtype H7N9 Assay**

As described in section IV below, Quidel Corporation is also authorized to make available additional information relating to the emergency use of the authorized Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 Assay in the specified population, when used on the specified instruments for presumptive detection of influenza A (H7N9) virus (detected in China in 2013), 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 Lyra™ Influenza A Subtype H7N9 Assay used on the specified instruments may be effective in the diagnosis of influenza A (H7N9) virus (detected in China in 2013) infection in the specified population 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 Lyra™ Influenza A Subtype H7N9 Assay, when used to diagnose influenza A (H7N9) virus (detected in China in 2013) 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 Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 Assay described above is authorized to diagnose influenza A (H7N9) virus (detected in China in 2013) infection on the specified instruments in the specified population.

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 Lyra™ Influenza A Subtype H7N9 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 Lyra™ Influenza A Subtype H7N9 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:

Quidel Corporation

A. Quidel Corporation will distribute the authorized Lyra™ Influenza A Subtype H7N9 Assay with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories or foreign laboratories.

B. Quidel Corporation will provide to the CLIA High Complexity Laboratories the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Healthcare Providers and the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Patients.

C. Quidel Corporation will make available on its website the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Healthcare Providers and the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Patients.

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

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Lyra™ Influenza A Subtype H7N9 Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized for use only by CLIA High Complexity Laboratories or foreign laboratories;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of influenza A (H7N9) virus (detected in China in 2013) and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the HHS declaration of emergency that justifies this authorization, unless the authorization is revoked sooner.

F. No advertising or promotional descriptive printed matter relating to the use of the authorized Lyra™ Influenza A Subtype H7N9 Assay may represent or suggest that this test has been found to be safe or effective for the diagnosis of influenza A (H7N9) virus (detected in China in 2013).

G. Quidel Corporation will ensure that CLIA High Complexity laboratories using the authorized Lyra™ Influenza A Subtype H7N9 Assay have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate.

H. Quidel Corporation will track adverse events and report to FDA as required under 21 CFR Part 803.

I. Through a process of inventory control, Quidel Corporation will maintain records of device usage.

J. Quidel Corporation 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 Quidel Corporation becomes aware.

K. Quidel Corporation is authorized to make available additional information relating to the emergency use of the authorized Lyra™ Influenza A Subtype H7N9 Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

L. Only Quidel Corporation may request changes to the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Healthcare Providers or the authorized Lyra™ Influenza A Subtype H7N9 Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

Page 6 – Dr. Tamerius, Quidel Corporation

CLIA High Complexity Laboratories

M. CLIA High Complexity Laboratories will include with reports of the results of the Lyra™ Influenza A Subtype H7N9 Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

N. CLIA High Complexity Laboratories will perform the assay on a bioMerieux NucliSENS® easyMAG® Nucleic Acid Extraction System and an Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with the appropriate software, respectively.

O. CLIA High Complexity 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.

P. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Quidel Corporation any suspected occurrence of false positive or false negative results of which CLIA High Complexity laboratories become aware.

Q. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the Lyra™ Influenza A Subtype H7N9 Assay that this test is only authorized for the diagnosis of influenza A (H7N9) virus (detected in China in 2013) and not for seasonal influenza A, B, or any other pathogen.

Quidel Corporation and CLIA High Complexity Laboratories

R. Quidel Corporation and CLIA High Complexity 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 Lyra™ Influenza A Subtype H7N9 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

Enclosures

Dated: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08706 Filed 4–16–14; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0331]

Live Case Presentations During Investigational Device Exemption Clinical Trials; Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff.'' This guidance is intended, in part, to improve the quality of information submitted by sponsors in an IDE application or supplement to an IDE application and to ensure consistency in the review of those submissions. This draft guidance is intended to clarify FDA's regulations and policies regarding live case