establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Comments

### *A. General Information About Submitting Comments*

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

### *B. Public Availability of Comments*

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on *http://www.regulations.gov.* This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *www.regulations.gov.* For this docket, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

### *C. Information Identifying the Person Submitting the Comment*

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your State/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

## IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: September 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–23001 Filed 9–11–15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–1206]**

### Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Ebola Zaire 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 Ebola Zaire virus in response to the Ebola virus outbreak in West Africa. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by OraSure Technologies, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the September 22, 2006, determination by then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security. On the basis of such determination, the Secretary of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic devices for detection of Ebola 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 July 31, 2015.

**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. 1, Rm. 4338, 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:** Carmen Maher, Acting Assistant Commissioner for Counterterrorism Policy and Acting Director, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, 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; or (4) the identification of a material threat by the Secretary of Homeland Security under 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 [1] 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 Ebola Zaire Virus

On September 22, 2006, then-Secretary of DHS, Michael Chertoff, determined that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security.[2] On August 5, 2014, 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 Ebola virus, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** on August 12, 2014 (79 FR 47141). On July 20, 2015, OraSure Technologies, Inc. requested, and on July 31, 2015, FDA issued, an EUA for the OraQuick® Ebola Rapid Antigen Test, subject to the terms of the 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 Ebola Zaire virus (detected in the West Africa outbreak in 2014) 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:

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[1] 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.

[2] Under section 564(b)(1) of the FD&C Act, the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat under section 319F–2 of the PHS Act sufficient to affect national security or the health and security of U.S. citizens living abroad (section 564(b)(1)(D) of the FD&C Act).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

July 31, 2015

Tiffany Miller
Director, Regulatory Affairs
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Dear Ms. Miller:

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 OraQuick® Ebola Rapid Antigen Test[1] for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014)[2] in venipuncture whole blood or fingerstick whole blood specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection), by laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). The OraQuick® Ebola Rapid Antigen Test is intended for circumstances when the use of a rapid Ebola virus test is determined to be more appropriate than the use of an authorized Ebola virus nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus. The OraQuick® Ebola Rapid Antigen Test is not intended for use for general Ebola virus infection screening, such as airport screening or contact tracing of individuals without signs and symptoms of Ebola infection.

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) 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.[3] 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 the

[1] For purposes of this authorization, the term "OraQuick® Ebola Rapid Antigen Test" includes, in addition to the OraQuick® Ebola Rapid Antigen Test Kit, the OraQuick® Ebola Rapid Antigen Test Kit Controls (quality control reagents intended for use only with the OraQuick® Ebola Rapid Antigen Test) and the OraQuick® Ebola Visual Reference Panel (intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device). While the OraQuick® Ebola Rapid Antigen Test Kit Controls and OraQuick® Ebola Visual Reference Panel are both sold separately, under this authorization they must be used in conjunction with the OraQuick® Ebola Rapid Antigen Test Kit.

[2] This assay is intended for the qualitative detection of antigens from Zaire Ebola virus (detected in the West Africa outbreak in 2014), but may also detect antigens from Sudan Ebola virus and Bundibugyo Ebola virus; however, it does not distinguish between these different Ebola virus species.

[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat pursuant to section 319F-2 of the PHS Act sufficient to affect national security or the health and security of United States citizens living abroad (section 564(b)(1)(D) of the Act).

Department of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)).[4]

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 OraQuick® Ebola Rapid Antigen Test (as described in the Scope of Authorization section of this letter (section II)) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection) (as described in the Scope of Authorization section of this letter (section II)) for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

**I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the OraQuick® Ebola Rapid Antigen Test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) 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 Ebola Zaire virus (detected in the West Africa outbreak in 2014) can cause Ebola virus disease, 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 OraQuick® Ebola Rapid Antigen Test may be effective in diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, and that the known and potential benefits of the OraQuick® Ebola Rapid Antigen Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) 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 OraQuick® Ebola Rapid Antigen Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.[5]

**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 OraQuick® Ebola Rapid Antigen Test by laboratories and facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics) for the presumptive detection of Ebola Zaire virus (detected in the

[4] U.S. Department of Health and Human Services. *Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus*. 79 Fed. Reg. 47141 (August 12, 2014).
[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

West Africa outbreak in 2014) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The authorized OraQuick® Ebola Rapid Antigen Test is intended for circumstances when use of a rapid Ebola virus test is determined to be more appropriate than use of an authorized Ebola virus nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus. The authorized OraQuick® Ebola Rapid Antigen Test is not intended for use for general Ebola infection screening, such as airport screening or contact tracing of individuals without signs and symptoms of Ebola infection.

**The Authorized OraQuick® Ebola Rapid Antigen Test**

The OraQuick® Ebola Rapid Antigen Test is a rapid single-use chromatographic lateral flow immunoassay contained within a rigid plastic device housing that is intended for the *in vitro* qualitative detection of antigens from the Ebola Zaire virus (detected in the West Africa outbreak 2014) in venipuncture whole blood, fingerstick whole blood, and other authorized specimen types from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The OraQuick® Ebola Rapid Antigen Test is a point-of-care test.

The OraQuick® Ebola Rapid Antigen Test utilizes a sandwich capture lateral flow immunoassay method to detect Ebola virus antigens. This lateral flow test is composed of an assay strip with several components: the flat pad, the blocker pad, the conjugate pad, the nitrocellulose membrane (with a Test Line ("T") and a Control ("C") line), and the absorbent pad. The clinical specimen is applied to the device followed by insertion of the device into the developer solution. The execution of the assay occurs as reagents are hydrated and liquid is transported along with the specimen across the strip towards the test zone.

If Ebola viral antigens are present in the patient sample they will be bound by biotinylated anti-Ebola polyclonal antibodies eluting from the blocker pad. These complexed Ebola antigens will then form immunological sandwiches with signal generating colloidal gold labeled Ebola antibodies that are eluting from the conjugate pad. The immunological sandwich complex is subsequently captured through reaction of the biotinylated anti-Ebola antibody with the biotin binding protein streptavidin that is immobilized at the Test Line ("T") of the test strip.

The OraQuick® Ebola Rapid Antigen Test Kit is comprised of an OraQuick® Ebola Rapid Antigen Test device, a filled, capped and labeled Developer Vial, a device stand (used to hold the device during the running of the test following specimen collection), micropipettes, a quick reference guide and the package insert. The test kit has a built-in procedural control that demonstrates assay validity. A purple line in the Control ("C") area of the Result Window indicates that the fluid migrated appropriately through the Test Device. The Control line will appear on all valid tests, whether or not the sample is positive (i.e., reactive) or negative (i.e., non-reactive).

The OraQuick® Ebola Rapid Antigen Test Kit Controls must be used with the OraQuick® Ebola Rapid Antigen Test. The OraQuick® Ebola Rapid Antigen Test Kit Controls contain two vials,

one Ebola positive control vial (orange capped) and one Ebola negative control vial (white capped).

The OraQuick® Ebola Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. It consists of three devices that have been specifically formulated and manufactured to represent positive results near the limit of detection, low positive, and negative test results. New operators must be able to correctly interpret all devices of the OraQuick® Ebola Visual Reference Panel prior to using the OraQuick® Ebola Rapid Antigen Test device with patient samples.

The above described OraQuick® Ebola Rapid Antigen Test, when labeled consistently with the labeling authorized by FDA entitled "OraQuick® Ebola Rapid Antigen Test Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by OraSure Technologies, Inc. in consultation with FDA, is authorized to be distributed to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics), despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described OraQuick® Ebola Rapid Antigen Test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care professionals and patients:

- Fact Sheet for Health Care Providers: Interpreting OraQuick® Ebola Rapid Antigen Test Results
- Fact Sheet for Patients: Understanding Results from the OraQuick® Ebola Rapid Antigen Test

As described in section IV below, OraSure Technologies, Inc. and any authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized OraQuick® Ebola Rapid Antigen Test 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 OraQuick® Ebola Rapid Antigen Test in the specified population, when used for presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014), 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 OraQuick® Ebola Rapid Antigen Test may be effective in the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available to FDA including the information supporting the conclusions described in section I above, and concludes that the authorized OraQuick® Ebola Rapid Antigen Test, when used to diagnose Ebola Zaire virus (detected in the West Africa

outbreak in 2014) 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 OraQuick® Ebola Rapid Antigen Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (section II) and the Conditions of Authorization (section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the OraQuick® Ebola Rapid Antigen Test described above is authorized to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA 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 OraQuick® Ebola Rapid Antigen Test during the duration of this EUA:

- 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 OraQuick® Ebola Rapid Antigen Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 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), (7), 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:

**OraSure Technologies, Inc. and Any Authorized Distributor(s)**

A. OraSure Technologies, Inc. and any authorized distributor(s) will distribute the authorized OraQuick® Ebola Rapid Antigen Test with the authorized labeling, as may be revised by OraSure Technologies, Inc. in consultation with FDA, to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics).

B. OraSure Technologies, Inc. and any authorized distributor(s) will provide to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics), the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Health Care Providers and the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Patients.

C. OraSure Technologies, Inc. and any authorized distributor(s) will make available on their websites the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Health Care Providers and the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Patients.

D. OraSure Technologies, Inc. and any authorized distributor(s) will inform laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. OraSure Technologies, Inc. and any authorized distributor(s) will ensure that first time users of the OraQuick® Ebola Rapid Antigen Test Kit will be informed about the requirement for use of the control material and the visual reference panel.

F. OraSure Technologies, Inc. and any authorized distributor(s) will ensure that laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) using the authorized OraQuick® Ebola Rapid Antigen Test have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

G. Through a process of inventory control, OraSure Technologies, Inc. and any authorized distributor(s) will maintain records of device usage.

H. OraSure Technologies, Inc. and any authorized distributor(s) 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 OraSure Technologies, Inc. and any authorized distributor(s) become aware.

I. OraSure Technologies, Inc. and any authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized OraQuick® Ebola Rapid Antigen Test that is consistent with, and does not exceed, the terms of this letter of authorization.

**OraSure Technologies, Inc.**

J. OraSure Technologies, Inc. will notify FDA of any authorized distributor(s) of the OraQuick® Ebola Rapid Antigen Test, including the name, address, and phone number of any authorized distributor(s).

K. OraSure Technologies, Inc. will provide any authorized distributor(s) with a copy of this EUA, and communicate to any authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

L. OraSure Technologies, Inc. only may request changes to the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Health Care Providers or the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Patients. Such requests will be made only by OraSure Technologies, Inc. in consultation with FDA.

M. OraSure Technologies, Inc. may request the addition of other specimen types for use with the authorized OraQuick® Ebola Rapid Antigen Test. Such requests will be made by OraSure Technologies, Inc. in consultation with, and require concurrence of, FDA.

N. OraSure Technologies, Inc. will track adverse events and report to FDA under 21 CFR Part 803.

**Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection (Including Treatment Centers and Public Health Clinics)**

O. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will include with reports of the results of the OraQuick® Ebola Rapid Antigen Test the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

P. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

Q. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will collect information on the performance of the assay, and report to OraSure Technologies, Inc. and any authorized distributor(s) any suspected occurrence of false positive or false negative results of which they become aware.

R. All personnel from laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) using the assay will be appropriately trained on the OraQuick® Ebola Rapid Antigen Test and use appropriate laboratory and personal protective equipment when handling this kit.

**OraSure Technologies, Inc., Any Authorized Distributor(s), and Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection (Including Treatment Centers and Public Health Clinics)**

S. OraSure Technologies, Inc., any authorized distributor(s), and laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) 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.

**Conditions Related to Advertising and Promotion**

T. All advertising and promotional descriptive printed matter relating to the use of the authorized OraQuick® Ebola Rapid Antigen Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

U. All advertising and promotional descriptive printed matter relating to the use of the authorized OraQuick® Ebola Rapid Antigen Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics);
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014); and
- This test is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized OraQuick® Ebola Rapid Antigen Test may represent or suggest that this test is safe or effective for the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

The emergency use of the authorized OraQuick® Ebola Rapid Antigen Test described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Page 9 – Ms. Miller, OraSure Technologies, Inc.

Sincerely,

Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

Dated: September 8, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–23003 Filed 9–11–15; 8:45 am]

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