TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section; [FDA Form No.]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
314.50(a), (b), (c), (d), (e), (f), (g), (i), (j), (k) and (l) [356h]	106	1.42	151	1,921	290,071
314.52	7	3	21	16	336
314.95	209	3	627	16	10,032
314.60	277	8.73	2,419	80	193,520
314.65	18	1.16	21	2	42
314.70 and 314.71	374	7.63	2,854	150	428,100
314.72	66	2.20	145	2	290
314.81(b)(1) [3331]	260	16.31	4,241	8	33,928
314.81(b)(2) [2252]	930	11.28	10,495	40	419,800
314.81(b)(3)(i) [2253]	520	87.43	45,461	2	90,922
314.94(a) and (d)	251	4.73	1,186	480	569,280
314.96	434	24.60	10,675	80	854,000
314.97	306	18.34	5,611	80	448,880
314.99(a)	219	3.01	659	2	1,318
314.101(a)	1	1	1	*.50	.50
314.420	524	1.98	1,038	61	63,318
314.550	20	7	140	120	16,800
Total					3,420,637.50

There are no capital costs or operating and maintenance costs associated with this collection of information.
*30 minutes.

Dated: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22088 Filed 9–16–14; 8:45 am]

BILLING CODE 4164–01–P

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 (detected in the West Africa outbreak in 2014). FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the U.S. Department of Defense (DoD). 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 diagnostics 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 August 5, 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. 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: 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. 1, Rm. 4340, 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 DHS 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 DoD 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 DHS 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 [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 August 4, 2014, DoD submitted a complete request for, and on August 5, 2014, FDA issued an EUA for the Ebola Zaire (Target 1) Real-Time PCR (TaqMan®) (EZ1 rRT–PCR) 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 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.

BILLING CODE 4164–01–P

[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] Pursuant to section 564(b)(1) of the FD&C 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 Secretary of DHS of a material threat pursuant to 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

August 5, 2014

Robert E. Miller, PhD, RAC
Director, Division of Regulated Activities and Compliance
Department of the Army
U.S. Army Medical Materiel Development Activity
1430 Veterans Drive
Fort Detrick, MD 21702-5009

Dear Dr. 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 U.S. Department of Defense (DoD) *Ebola Zaire (Target 1)* Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) on specified instruments in individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors, by laboratories designated by DoD, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

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.[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 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 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 EZ1 rRT-PCR Assay (as described in the Scope of Authorization section of this letter (Section II)) in individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors (as described in the Scope of Authorization section of this letter (Section II)) for the presumptive detection of Ebola Zaire

[1] 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).
[2] U.S. Department of Health and Human Services. *Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b).* August 5, 2014.

virus (detected in the West Africa outbreak in 2014) by laboratories designated by DoD, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the EZ1 rRT-PCR Assay 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 hemorrhagic fever, 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 EZ1 rRT-PCR Assay, when used with the specified instruments, may be effective in diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014), and that the known and potential benefits of the EZ1 rRT-PCR Assay, when used with the specified instruments 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 EZ1 rRT-PCR Assay for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014).[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 EZ1 rRT-PCR Assay by laboratories designated by DoD for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors.

The Authorized EZ1 rRT-PCR Assay:

The EZ1 rRT-PCR Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in Trizol-inactivated whole blood or Trizol-inactivated plasma specimens from individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors. The test procedure consists of nucleic

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

acid extraction followed by rRT-PCR on only the ABI 7500 FAST DX instrument, the JBAIDS instrument, or the Roche LightCycler instrument.

The EZ1 rRT-PCR Assay consists of two primer/probe sets: EZ1 and RNase P along with the assay master mix and Positive Template Controls (PTC) for each primer/probe set. RNA is extracted from Trizol-inactivated whole blood collected with EDTA as the anticoagulant, or Trizol-inactivated plasma, using the Qiagen QIAamp Viral RNA Mini Kit, purchased separately from the assay, prior to running on an authorized instrument. The QIAamp Viral RNA Mini Kit simplifies purification of viral RNA from Trizol-inactivated whole blood with a fast spin-column procedure. Viral RNA binds specifically to the QIAamp silica membrane, and pure viral RNA is eluted in the buffer provided with the kit. The resulting purified RNA is analyzed on one of the authorized instruments using provided Ebola Zaire and RNase P master mixes with appropriate controls in place.

The EZ1 rRT-PCR Assay includes the following assay controls:

- **RNTC** (Reagents No Template Control) is a negative control used in the amplification step to demonstrate no reagent contamination.
- **SNTC** (Sample Negative Control) is a negative control used in the amplification step to demonstrate no contamination in the sample loading.
- **EZ1 PTC** (Positive Template Control) is a positive control used in the amplification step to confirm target amplification and EZ1 reagent function.
- **RP-PTC** (RNase P Positive Template Control) is a positive control used in the amplification step to ensure the RNase P reagents function.
- **NPC** (Negative Processing Control) is a processing control used during the extraction step to demonstrate that no cross contamination occurred.

The above described EZ1 rRT-PCR Assay, when labeled consistently with the labeling authorized by FDA entitled "*Ebola Zaire (Target 1)* Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay on ABI® 7500 Fast Dx, LightCycler®, and JBAIDS: Instruction Booklet" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by DoD in consultation with FDA, is authorized to be distributed to and used by laboratories designated by DoD under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described EZ1 rRT-PCR Assay 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 *Ebola Zaire (Target 1)* Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Assay Results**

- **Fact Sheet for Patients: Understanding Results from the *Ebola Zaire (Target 1)* Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Test**

As described in Section IV below, DoD is also authorized to make available additional information relating to the emergency use of the authorized EZ1 rRT-PCR 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 EZ1 rRT-PCR Assay 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 EZ1 rRT-PCR Assay 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. The 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 EZ1 rRT-PCR Assay, when used to diagnose of 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 EZ1 rRT-PCR Assay 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 EZ1 rRT-PCR Assay described above is authorized to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors.

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 EZ1 rRT-PCR Assay 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 EZ1 rRT-PCR Assay.

- 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:

U.S. Department of Defense (DoD)

A. DoD will distribute the authorized EZ1 rRT-PCR Assay with the authorized labeling, as may be revised by DoD in consultation with FDA, only to laboratories designated by DoD.

B. DoD will provide to laboratories designated by DoD the authorized EZ1 rRT-PCR Assay Fact Sheet for Health Care Providers and the authorized EZ1 rRT-PCR Assay Fact Sheet for Patients.

C. DoD will make available on its website the authorized EZ1 rRT-PCR Assay Fact Sheet for Health Care Providers and the authorized EZ1 rRT-PCR Assay Fact Sheet for Patients.

D. DoD will inform laboratories designated by DoD and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. DoD will ensure that laboratories designated by DoD using the authorized EZ1 rRT-PCR Assay have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

F. DoD will track adverse events and report to FDA under 21 CFR Part 803.

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

H. DoD 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 DoD becomes aware.

I. DoD is authorized to make available additional information relating to the emergency use of the authorized EZ1 rRT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Only DoD may request changes to the authorized EZ1 rRT-PCR Assay Fact Sheet for Health Care Providers or the authorized EZ1 rRT-PCR Assay Fact Sheet for Patients. Such requests will be made by DoD in consultation with FDA.

Laboratories Designated by DoD

K. Laboratories designated by DoD will include with reports of the results of the EZ1 rRT-PCR Assay 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.

L. Laboratories designated by DoD will perform the EZ1 assay only on the ABI 7500 FAST DX instrument, JBAIDS instrument, or Roche LightCycler instrument.

M. Laboratories designated by DoD will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

N. Laboratories designated by DoD will collect information on the performance of the assay, and report to DoD any suspected occurrence of false positive or false negative results of which they become aware.

O. All laboratory personnel using the assay should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit.

DoD and Laboratories Designated by DoD

P. DoD and laboratories designated by DoD 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

Q. All advertising and promotional descriptive printed matter relating to the use of the authorized EZ1 rRT-PCR Assay 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.

R. All advertising and promotional descriptive printed matter relating to the use of the authorized EZ1 rRT-PCR Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization for use by laboratories designated by DoD;
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) and not for any other viruses or pathogens; and

Page 7 – Dr. Miller, U.S. Department of Defense

- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola Zaire 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.

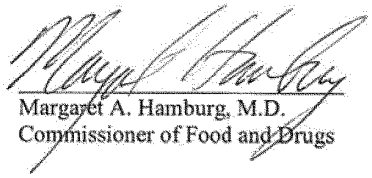
No advertising or promotional descriptive printed matter relating to the use of the authorized EZ1 rRT-PCR Assay may represent or suggest that this test is safe or effective for the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

The emergency use of the authorized EZ1 rRT-PCR Assay as 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.

Sincerely,



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

Enclosures

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22086 Filed 9–16–14; 8:45 am]

BILLING CODE 4164–01–C