rubrum and *Epidermophyton floccosum* in patients 18 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for LUZU (U.S. Patent No. 5,900,488) from Nihon Nohyaku Co., Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LUZU represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LUZU is 2,242 days. Of this time, 1,903 days occurred during the testing phase of the regulatory review period, while 339 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* September 27, 2007. FDA has verified the Nihon Nohyaku Co., Ltd. claim that September 27, 2007, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 11, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for LUZU (NDA 204153) was initially submitted on December 11, 2012.

3. *The date the application was approved:* November 14, 2013. FDA has verified the applicant's claim that NDA 204153 was approved on November 14, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,289 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09374 Filed 4–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0969]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika 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 Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the U.S. Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Department of Health and Human Services (HHS) Secretary 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 Zika virus. On the basis of such determination, the HHS Secretary declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection 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 March 17, 2016.

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, 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 360(e)), 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 CDC (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.

[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.

II. EUA Request for an In Vitro Diagnostic Device for Detection of Zika Virus

On February 26, 2016, 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 Zika virus. On February 26, 2016, 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 diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On March 14, 2016, CDC requested, and on March 17, 2016, FDA issued, an EUA for the CDC Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR), 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 Zika virus subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 17, 2016

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

Dear Dr. Frieden:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention's (CDC) Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) for the qualitative detection and differentiation of RNA from Zika virus, dengue virus, and chikungunya virus in human sera or cerebrospinal fluid (collected alongside a patient-matched serum specimen), and for the qualitative detection of Zika virus RNA in urine and amniotic fluid (each collected alongside a patient-matched serum specimen), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). The assay is intended for use with specimens collected from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health investigation), by qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.[1] Assay results are for the identification of Zika, dengue, and chikungunya viral RNA. Viral RNA is generally detectable in serum during the acute phase of infection (approximately 7 days following onset of symptoms, if present). Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C), the Secretary 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 Zika virus.[2] 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

[1] For ease of reference, this letter will refer to "qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

[2] 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.

exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[3]

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 Trioplex rRT-PCR (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health investigation) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Trioplex rRT-PCR for the detection of Zika virus and diagnosis of Zika virus infection 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 Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Trioplex rRT-PCR, when used with the specified instrument and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Trioplex rRT-PCR for detecting of Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Trioplex rRT-PCR for diagnosing Zika virus infection.[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 Trioplex rRT-PCR by authorized laboratories for the detection and differentiation of RNA from Zika virus, dengue virus, and chikungunya virus in human sera or cerebrospinal fluid (collected alongside a patient-matched serum specimen), and for the detection of Zika virus RNA in urine and amniotic fluid (each collected alongside a

[3] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection.* .81 Fed. Reg. 10878 (March 2, 2016).

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

patient-matched serum specimen), in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health investigation).

The Authorized Trioplex rRT-PCR

The CDC Trioplex rRT-PCR is a real-time reverse transcriptase PCR (rRT-PCR) for the in vitro qualitative detection and differentiation of Zika virus, dengue virus, and chikungunya virus in sera, CSF, and other authorized specimen types collected from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health investigation). The Trioplex rRT-PCR can also be used with urine and amniotic fluid specimens when tested in conjunction with a patient-matched serum specimen and other authorized whole blood derived specimen types. The test procedure consists of nucleic acid extraction using the MagNA Pure LC Total Nucleic Acid Isolation Kit, the Qiagen QIAamp® Viral RNA Mini kit or other authorized extraction method, followed by rRT-PCR on the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument or other authorized instruments using SuperScript™ III RT/Platinum® One-Step qRT-PCR Kit, Quanta qScript™ One-Step qRT-PCR Kit, Low Rox™ or other authorized PCR enzyme Kits.

The Trioplex rRT-PCR includes primers and dual-labeled hydrolysis (Taqman®) probes to be used in the in vitro qualitative detection of Zika virus RNA isolated from clinical specimens including serum (from serum separator tubes), CSF, urine, and amniotic fluid, and any other authorized specimens. A reverse transcription step produces cDNA from RNA present in the sample. The probe binds to the target DNA between the two unlabeled PCR primers. For the dengue virus-specific probe, the signal from the fluorescent dye (FAM) on the 5' end is quenched by BHQ-1 on its 3' end. For the chikungunya virus-specific probe, the signal from the fluorescent dye (HEX) on the 5' end is quenched by BHQ-1 on its 3' end. For the Zika virus-specific probe, the signal from the fluorescent dye (Texas Red [TxRd]) on the 5'end is quenched by BHQ-2 on its 3' end. During PCR, Taq polymerase extends the unlabeled primers using the template strand as a guide, and when it reaches the probe it cleaves the probe separating the dye from the quencher allowing it to fluoresce. The Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument and other authorized instruments detect this fluorescence from the unquenched dye. With each cycle of PCR, more probes are cleaved resulting in an increase in fluorescence that is proportional to the amount of target nucleic acid present. Testing is performed in a 96 well plate format.

The Trioplex rRT-PCR includes the following materials:

- CDC Trioplex rRT-PCR Primer and Probe sets for the detection of dengue virus (DENV), chikungunya virus (CHIKV), Zika virus (ZIKV) and the extraction control RNAse P (RP).

  - DENV-F, DENV-R1, DENV-R2, and P
  - CHIKV-F, R and P
  - ZIKV-F, R and P
  - RP-F, R and P

- Trioplex Real-Time RT-PCR Positive Control Set
  - Inactivated dengue virus
  - Inactivated chikungunya virus
  - Inactivated Zika virus
  - Human specimen control - extraction control and positive control for RP

The Trioplex rRT-PCR requires the following control materials; all assay controls listed below should be run concurrently with all test samples and must generate expected results in order for a test to be considered valid:

- **Human specimen control (HSC)**
  Noninfectious cultured human cell material used as an extraction control and positive control for the RNase P primer and probe set (RP) that is extracted and tested concurrently with the test samples.

- **Positive controls for agent-specific primer and probe sets**
  - Inactivated dengue virus
  - Inactivated chikungunya virus
  - Inactivated Zika virus

- **RNase P Primer and Probe Set (RP)**
  All clinical samples and the HSC should be tested for human RNase P gene (using the RP primer and probe set included in the Trioplex rRT-PCR kit) to control for specimen quality and as an indicator that nucleic acid resulted from the extraction process.

- **No Template Control (NTC)**
  NTC reactions include PCR-grade water in place of specimen RNA and must be included as a contamination control for each reaction mixture (one for the ZIKV, CHIKV and DENV reaction and one for the RP reaction) in each run.

The above described Trioplex rRT-PCR, when labeled consistently with the labeling authorized by FDA entitled "Trioplex Real-Time RT-PCR Assay - Instructions for Use" (available at http://www.fda.gov/MedicalDevices/%20Safety/EmergencySituations/ucm161496.htm), which may be revised by CDC in consultation with FDA, is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Trioplex rRT-PCR is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to

health care providers, pregnant women, and other patients:

- Fact Sheet for Health Care Providers: Interpreting Trioplex Real-Time RT-PCR Assay (Trioplex rRT-PCR) Results
- Fact Sheet for Pregnant Women: Understanding Results from the Trioplex Real-Time RT-PCR Assay (Trioplex rRT-PCR)
- Fact Sheet for Patients: Understanding Results from the Trioplex Real-Time RT-PCR Assay (Trioplex rRT-PCR)

As described in Section IV below, CDC is also authorized to make available additional information relating to the emergency use of the authorized Trioplex rRT-PCR 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 Trioplex rRT-PCR in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), 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 Trioplex rRT-PCR may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), 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 Trioplex rRT-PCR, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Trioplex rRT-PCR 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 HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Trioplex rRT-PCR described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to geographic regions during a period of active Zika virus transmissions at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health investigation).

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 Trioplex rRT-PCR 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 Trioplex rRT-PCR.

- 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:

Centers for Disease Control and Prevention (CDC)

A. CDC will distribute the authorized Trioplex rRT-PCR with the authorized labeling, as may be revised by CDC in consultation with FDA, only to authorized laboratories.

B. CDC will provide to authorized laboratories the authorized Trioplex rRT-PCR Fact Sheet for Health Care Providers, the authorized Trioplex rRT-PCR Fact Sheet for Pregnant Women, and the authorized Trioplex rRT-PCR Fact Sheet for Patients.

C. CDC will make available on its website the authorized Trioplex rRT-PCR Fact Sheet for Health Care Providers, the authorized Trioplex rRT-PCR Fact Sheet for Pregnant Women, and the authorized Trioplex rRT-PCR Fact Sheet for Patients.

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

E. CDC will ensure that authorized laboratories using the authorized Trioplex rRT-PCR have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.

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

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

H. CDC will collect information on the performance of the assay. CDC will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the assay of which CDC becomes aware.

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

J. CDC may request changes to the authorized Trioplex rRT-PCR Fact Sheet for Health Care Providers, the authorized Trioplex rRT-PCR Fact Sheet for Pregnant Women, and the authorized Trioplex rRT-PCR Fact Sheet for Patients. Such requests will be made by CDC in consultation with FDA, and require concurrence of, FDA.

K. CDC may request the addition of other real-time PCR instruments for use with the authorized Trioplex rRT-PCR. Such requests will be made by CDC in consultation with, and require concurrence of, FDA.

L. CDC may request the addition of other extraction methods for use with the authorized Trioplex rRT-PCR. Such requests will be made by CDC in consultation with, and require concurrence of, FDA.

M. CDC may request the addition of other specimen types for use with the authorized Trioplex rRT-PCR. Such requests will be made by CDC in consultation with, and require concurrence of, FDA.

N. CDC will assess traceability[5] of the Trioplex rRT-PCR with the interim WHO Zika reference standard when the reference material becomes available. After submission to FDA and FDA's review of and concurrence with the data, CDC will update their labeling to reflect the additional testing.

Authorized Laboratories

O. Authorized laboratories will include with reports of the results of the Trioplex rRT-PCR, the authorized Fact Sheet for Health Care Providers, the authorized Fact Sheet for Pregnant Women, 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. Authorized laboratories will perform the Trioplex rRT-PCR on the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument or other authorized instruments.

[5] Traceability refers to tracing analytical sensitivity/reactivity back to the interim WHO Zika reference material.

Q. Authorized laboratories will have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.

R. Authorized laboratories will collect information on the performance of the assay and report to CDC any suspected occurrence of false positive or false negative results of which they become aware.

S. 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.

CDC and Authorized Laboratories

T. CDC and authorized 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.

Conditions Related to Advertising and Promotion

U. All advertising and promotional descriptive printed matter relating to the use of the authorized Trioplex rRT-PCR 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.

V. All advertising and promotional descriptive printed matter relating to the use of the authorized Trioplex rRT-PCR 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 authorized laboratories;
- This test has been authorized only for the detection and differentiation of RNA from Zika virus, dengue virus, and chikungunya virus, and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection 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 Trioplex rRT-PCR may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

Page 9 – Dr. Frieden, Centers for Disease Control and Prevention

The emergency use of the authorized Trioplex rRT-PCR 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* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: April 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09370 Filed 4–21–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0321]

Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice entitled ''Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments'' that appeared in the **Federal Register** of March 4, 2016. The notice requested scientific data, information, and comments that would assist in the development of a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure). We are taking this action for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by July 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–0321 for ''Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the