Application No.	Drug
065102	Amoxicillin and Clavulanate Potassium Tablets USP, 875 mg/EQ 125 mg base.
065109	Amoxicillin and Clavulanate Potassium Tablets USP, 500 mg/EQ 125 mg base.
065113	Amoxicillin for Oral Suspension USP, 200 mg/5 mL and 400 mg/5 mL.
065115	Cefadroxil for Oral Suspension USP, EQ 125 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 500 mg base/5 mL.
065118	Cefuroxime Axetil Tablets USP, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base.
065132	Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/EQ 28.5 mg base per 5 mL and 400 mg/EQ 57 mg base per 5 mL.
065161	Amoxicillin and Clavulanate Potassium Tablets USP (Chewable), 200 mg/EQ 28.5 mg base and 400 mg/EQ 57 mg base.
065207	Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 600 mg/EQ 42.9 mg base per 5 mL.
065323	Cefuroxime Axetil for Oral Suspension USP, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL.
074975	Acyclovir Capsules USP, 200 mg.
074980	Acyclovir Tablets USP, 400 mg and 800 mg.
075132	Ranitidine Tablets USP, EQ 75 mg base.
075439	Ranitidine Tablets USP, EQ 150 mg base and EQ 300 mg base.
076041	Sotret (isotretinoin) Capsules USP, 10 mg, 20 mg, and 40 mg.
076285	Simvastatin Tablets USP, 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg.
076332	Fluconazole for Oral Suspension, 10 mg/mL and 40 mg/mL.
076409	Nefazodone Hydrochloride Tablets USP, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg.
076503	Sotret (isotretinoin) Capsules USP, 30 mg.
076606	Gabapentin Capsules USP, 100 mg, 300 mg, and 400 mg.
076739	Fosinopril Sodium and Hydrochlorothiazide Tablets USP, 10 mg/12.5 mg and 20 mg/12.5 mg.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective January 19, 2017.

Dated: December 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30623 Filed 12–19–16; 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 the 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 Abbott Molecular, Inc. 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 Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS 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 November 21, 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 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.

[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 the 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 November 9, 2016, Abbott Molecular, Inc. requested, and on November 21, 2016, FDA issued, an EUA for the Abbott Real Time ZIKA assay, 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 *https://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

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

November 21, 2016

Stacy Ferguson
Regulatory Affairs Project Manager
Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018

Dear Ms. Ferguson:

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 Abbott Molecular Inc.'s ("Abbott") RealTi*me* ZIKA assay for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, and urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting Centers for Disease Control and Prevention (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 epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[2] up to 14 days in serum and urine (possibly longer in urine), following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 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 U.S. citizens living abroad and that involves Zika virus.[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 HHS then declared 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, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

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

[2] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on November 16, 2016).

[3] 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 significant potential for a public health emergency.

[4] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika*

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 Abbott RealTi*me* ZIKA assay (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 epidemiological criteria for which Zika virus testing may be indicated) (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 Abbott RealTi*me* ZIKA assay 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 Abbott RealTi*me* ZIKA assay, when used with the specified instrument(s) 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 Abbott RealTi*me* Zika assay for detecting 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 Abbott RealTi*me* ZIKA assay for detecting Zika virus and diagnosing Zika virus 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 Abbott RealTi*me* ZIKA assay by authorized laboratories for the detection of RNA from Zika virus and diagnosis of 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 a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

The Authorized Abbott RealTi*me* ZIKA assay

The Abbott RealTi*me* ZIKA assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, EDTA

Virus and/or Diagnosis of Zika Virus Infection. 81 Fed. Reg. 10878 (March 2, 2016).

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

plasma, urine (collected alongside a patient-matched serum or plasma specimen) and other authorized specimen types.

To perform the Abbott RealTi*me* ZIKA assay, nucleic acids are isolated from the sample and purified using the Abbott *m*Sample Preparation System on the Abbott *m*2000*sp* instrument, an automated instrument for performing sample preparation, or other authorized instruments. Magnetic microparticle technology captures nucleic acids, and the particles are washed to remove unbound sample components. The bound nucleic acids are eluted and transferred to a 96 deep-well plate. The purified nucleic acid is reverse transcribed into cDNA which is then amplified in the Abbott *m*2000*rt* instrument, or other authorized instruments. This is followed by the detection of the target of interest.

The Abbott RealTi*me* ZIKA assay uses the following materials, or other authorized materials or ancillary products:

- Abbott *m*Sample Preparation System, containing
  - Abbott *m*Lysis
  - *m*Wash 1
  - *m*Wash 2
  - *m*Elution Buffer
  - *m*Microparticles reagent bottles

- Abbott RealTi*me* ZIKA Amplification Reagent Kit, containing
  - Abbott RealTi*me* ZIKA Internal Control in negative human serum
  - Abbott RealTi*me* ZIKA Amplification Reagent (Thermostable rTth Polymerase Enzyme; ZIKA Amplification Reagent with primers, probes and nucleotides; Activation Reagent)

The Abbott RealTi*me* ZIKA assay requires the following control materials, or other authorized control materials, to be included in each run; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Abbott RealTi*me* ZIKA Instructions for Use:

- Abbott RealTi*me* ZIKA Control Kit
  - Abbott RealTi*me* ZIKA Negative Control: Negative human plasma is used for monitoring of contaminations.
  - Abbott RealTi*me* ZIKA Positive Control: Inactivated Zika virus (strain PRVABC59) in human serum monitors for substantial reagent failure and is used throughout the extraction and PCR set-up for each run.

- Internal Control: noninfectious Armored RNA with internal control sequences in negative human plasma. It confirms the validity of the extraction process and identifies potential PCR inhibition; it is used throughout the extraction and PCR set-up for each sample.

To produce a valid run the test controls must meet the performance specifications outlined in the Abbott RealTi*me* ZIKA Instructions for Use.

The Abbott RealTi*me* ZIKA assay also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized Abbott RealTi*me* ZIKA Instructions for Use.

The above described Abbott RealTi*me* ZIKA assay, when labeled consistently with the labeling authorized by FDA entitled "Abbott RealTi*me* ZIKA Instructions for Use" and "Abbott RealTi*me* ZIKA Control Kit" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Abbott in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), 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 Abbott RealTi*me* ZIKA assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting Abbott RealTi*me* ZIKA Assay Results
- Fact Sheet for Patients: Understanding Results from the Abbott RealTi*me* ZIKA Assay

As described in Section IV below, Abbott and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized Abbott RealTi*me* ZIKA 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 Abbott RealTi*me* ZIKA assay 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 Abbott RealTi*me* ZIKA assay 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 Abbott RealTi*me* ZIKA assay, 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 Abbott RealTi*me* ZIKA 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 HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Abbott RealTi*me* ZIKA assay 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 a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

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 Abbott RealTi*me* ZIKA 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 Abbott RealTi*me* ZIKA 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:

Abbott Molecular Inc. and Its Authorized Distributor(s)

A. Abbott and its authorized distributor(s) will distribute the authorized Abbott RealTi*me* ZIKA assay with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. Abbott and its authorized distributor(s) will provide to authorized laboratories the authorized Abbott RealTi*me* ZIKA assay Fact Sheet for Healthcare Providers and the authorized Abbott RealTi*me* ZIKA assay Fact Sheet for Patients.

C. Abbott and its authorized distributor(s) will make available on their websites the

authorized Abbott RealTi*me* ZIKA assay Fact Sheet for Healthcare Providers and the authorized Abbott RealTi*me* ZIKA assay Fact Sheet for Patients.

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

E. Abbott and its authorized distributor(s) will ensure that the authorized laboratories using the authorized Abbott RealTi*me* ZIKA assay have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[6]

F. Through a process of inventory control, Abbott and its authorized distributor(s) will maintain records of device usage.

G. Abbott and its authorized distributor(s) will collect information on the performance of the test. Abbott will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Abbott becomes aware.

H. Abbott and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Abbott RealTi*me* ZIKA assay that is consistent with, and does not exceed, the terms of this letter of authorization.

Abbott Molecular Inc.

I. Abbott will notify FDA of any authorized distributor(s) of the Abbott RealTi*me* ZIKA assay, including the name, address, and phone number of any authorized distributor(s).

J. Abbott will provide its authorized distributor(s) with a copy of this EUA, and communicate to its 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).

K. Abbott may request changes to the authorized Abbott RealTi*me* ZIKA assay Fact Sheet for Healthcare Providers and the authorized Abbott RealTi*me* ZIKA assay Fact Sheet for Patients. Such requests will be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. Abbott may request the addition of other instruments for use with the authorized Abbott RealTi*me* ZIKA assay. Such requests will be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

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[7] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Abbott, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see http://www.cdc.gov/zika/).

M. Abbott may request the addition of other extraction methods for use with the authorized Abbott RealTi*me* ZIKA assay. Such requests will be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. Abbott may request the addition of other specimen types for use with the authorized Abbott RealTi*me* ZIKA assay. Such requests will be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. Abbott may request the addition of other control materials for use with the authorized Abbott RealTi*me* ZIKA assay. Such requests will be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. Abbott may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Abbott RealTi*me* ZIKA assay. Such requests will be made by Abbott in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. Abbott will assess traceability[7] of the Abbott RealTi*me* ZIKA assay with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Abbott will update its labeling to reflect the additional testing.

R. Abbott, assuming the medical device reporting responsibilities of the manufacturer of the Abbott RealTi*me* ZIKA assay, will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

S. Authorized laboratories will include with reports of the results of the Abbott RealTi*me* ZIKA assay the authorized Fact Sheet for Healthcare 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.

T. Authorized laboratories will perform the Abbott RealTi*me* ZIKA assay using nucleic acid extraction and PCR set-up procedures automated by the Abbott *m*2000*sp* instruments, or other authorized instruments.

U. Authorized laboratories will perform the Abbott RealTi*me* ZIKA assay on the Abbott *m*2000*rt* instrument, or other authorized instruments.

V. Authorized laboratories will perform the Abbott RealTi*me* ZIKA assay using the Abbott *m*Sample Preparation System for nucleic acid extraction, or other authorized extraction methods.

W. Authorized laboratories will perform the Abbott RealTi*me* ZIKA assay on human serum, EDTA plasma, or urine (collected alongside a patient-matched serum or plasma specimen) or other authorized specimen types.

[7] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.

X. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[8]

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

Z. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

Abbott Molecular Inc., Its Authorized Distributor(s) and Authorized Laboratories

AA. Abbott, its authorized distributor(s), 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

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized Abbott RealTi*me* ZIKA 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.

CC. All advertising and promotional descriptive printed matter relating to the use of the authorized Abbott RealTi*me* ZIKA 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 EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, 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.

[8] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Abbott, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

Page 9 – Ms. Stacy Ferguson, Abbott Molecular Inc., USA

No advertising or promotional descriptive printed matter relating to the use of the authorized Abbott RealTi*me* ZIKA assay may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Abbott RealTi*me* ZIKA 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* 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: December 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30532 Filed 12–19–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–0626]

Determination of Regulatory Review Period for Purposes of Patent Extension; COSENTYX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COSENTYX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 21, 2017. 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 by June 19, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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–E–0626 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; COSENTYX.'' 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