accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ZILVER PTX DRUG ELUTING PERIPHERAL STENT. ZILVER PTX DRUG ELUTING PERIPHERAL STENT is indicated for improving luminal diameter for the treatment of *de novo* or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameters from 4 millimeters (mm) to 9 mm and total lesion lengths up to 140 mm per limb and 280 mm per patient. Subsequent to this approval, the USPTO received a patent term restoration application for ZILVER PTX DRUG ELUTING PERIPHERAL STENT (U.S. Patent No. 6,299,604) from Cook Medical Technologies, LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 25, 2014, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ZILVER PTX DRUG ELUTING PERIPHERAL STENT 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 ZILVER PTX DRUG ELUTING PERIPHERAL STENT is 3,075 days. Of this time, 2,180 days occurred during the testing phase of the regulatory review period, while 895 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* June 16, 2004. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective was June 16, 2004.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* June 4, 2010. FDA has verified the applicant's claim that the premarket approval application (PMA) for ZILVER PTX DRUG ELUTING PERIPHERAL STENT (PMA P100022) was initially submitted June 4, 2010.

3. *The date the application was approved:* November 14, 2012. FDA has verified the applicant's claim that PMA P100022 was approved on November 14, 2012.

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 1,826 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: June 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14356 Filed 6–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1486]

Authorizations of Emergency Use of In Vitro Diagnostic Devices 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 two Emergency Use Authorizations (EUAs) (the Authorizations) for two in vitro diagnostic devices for detection of Zika virus in response to the Zika virus outbreak in the Americas. FDA issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Focus Diagnostics, Inc., and altona Diagnostics GmbH. The Authorizations contain,

among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow 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 Authorizations, which include explanations of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Focus Diagnostics, Inc., is effective as of April 28, 2016, and the Authorization for altona Diagnostics GmbH is effective as of May 13, 2016.

ADDRESSES: Submit written requests for single copies of the EUAs 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 Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

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.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Requests for In Vitro Diagnostic Devices 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

[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.

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 April 26, 2016, Focus Diagnostics, Inc., requested, and on April 28, 2016, FDA issued, an EUA for the Zika Virus RNA Qualitative Real-Time RT–PCR test, subject to the terms of the Authorization. On May 11, 2016, altona Diagnostics GmbH requested, and on May 13, 2016, FDA issued, an EUA for the RealStar® Zika Virus RT–PCR Kit U.S., subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at *http://www.regulations.gov.*

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of two in vitro diagnostic devices for detection of Zika virus subject to the terms of the Authorizations. The Authorizations in their entirety (not including the authorized versions of the fact sheets and other written materials) follow and provide explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 28, 2016

Michael J. Wagner, Esq.
Senior Corporate Counsel
Focus Diagnostics, Inc.
11331 Valley View Street
Cypress, CA 90630

Dear Mr. Wagner:

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 Focus Diagnostics, Inc.'s Zika Virus RNA Qualitative Real-Time RT-PCR test for the qualitative detection of RNA from Zika virus in human serum specimens 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 epidemiologic criteria for which Zika virus testing may be indicated), by qualified laboratories designated by Focus Diagnostics, Inc. 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, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Assay results are for the identification of Zika viral RNA. Zika 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 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]

[1] For ease of reference, this letter will refer to "qualified laboratories designated by Focus Diagnostics, Inc. 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.

[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).

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 Zika Virus RNA Qualitative Real-Time RT-PCR test (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 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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-PCR 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 Zika Virus RNA Qualitative Real-Time RT-PCR for detecting Zika virus and 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 Zika Virus RNA Qualitative Real-Time RT-PCR 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 epidemiologic criteria for which Zika virus testing may be indicated).

The Authorized Zika Virus RNA Qualitative Real-Time RT-PCR

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

Focus Diagnostics, Inc.'s Zika Virus RNA Qualitative Real-Time RT-PCR is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of Zika virus RNA in serum 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). The Zika Virus RNA Qualitative Real-Time RT-PCR can also be used with other authorized specimen types. The test procedure consists of nucleic acid extraction using the Roche MagNA Pure LC Total Nucleic Acid Isolation Large Volume Kit on the Roche MagNA Pure LC System, or other authorized extraction method, followed by rRT-PCR on the Applied Biosystems (ABI) 7500 Real-Time PCR System or other authorized instruments, using the Life Technologies SuperScript® III Platinum® One-Step Quantitative RT-PCR System, or other authorized PCR enzyme Kits.

The Zika Virus RNA Qualitative Real-Time RT-PCR includes primers and dual-labeled hydrolysis (Taqman®) probes targeting two separate nucleotide sequences within the Zika virus genome to be used in the *in vitro* qualitative detection of Zika virus RNA isolated from human serum and any other authorized specimens. The purified nucleic acids are first reverse transcribed into cDNAs. In the process, the probes anneal to the specific target sequences located between the respective forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probes, causing the reporter dyes to separate from the quencher dyes, generating fluorescent signals. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity.

The Zika Virus RNA Qualitative Real-Time RT-PCR kit includes the following materials:

- Zika Virus RNA Qualitative Real-Time RT-PCR Primer and Probe sets for the detection of Zika virus and the Internal Control
  - ZV RTPCR Mix 1 (contains SuperScript® III reaction buffer, primers, and probes for the "M" region of the Zika virus genome and the Internal Control)
  - ZV RTPCR Mix 2 (contains SuperScript® III reaction buffer, primers, and probes for the "env" region of the Zika virus genome and the Internal Control)

The Zika Virus RNA Qualitative Real-Time RT-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:

- **Zika Virus RNA Qualitative Real-Time RT-PCR Negative Control**
  - Normal human serum, no detectable Zika virus RNA
  - One included in each batch of specimen extraction to monitor Zika virus contamination

- **Zika Virus RNA Qualitative Real-Time RT-PCR Positive Control**
  - Zika virus strain FLR diluted in normal human serum
  - One included in each batch of specimen extraction to monitor nucleic acid isolation and detection of Zika virus RNA

- **Zika Virus RNA Qualitative Real-Time RT-PCR Internal Control**
  - DNA target included in each specimen, Positive Control, and Negative Control
  - Consists of a portion of the *Arabidopsis thaliana* genome, added to the lysis reagent provided in the MagNA Pure LC Total Nucleic Acid Large Volume Isolation Kit
  - Ensures the absence of non-specific PCR inhibition of a sample

The above described Zika Virus RNA Qualitative Real-Time RT-PCR, when labeled consistently with the labeling authorized by FDA entitled "Zika Virus RNA Qualitative Real-Time RT-PCR Instructions for Use" (available at http://www.fda.gov/MedicalDevices/%20Safety/EmergencySituations/ucm161496.htm), which may be revised by Focus Diagnostics, Inc. 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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-PCR Test Results
- Fact Sheet for Pregnant Women: Understanding Results from the Zika Virus RNA Qualitative Real-Time RT-PCR Test
- Fact Sheet for Patients: Understanding Results from the Zika Virus RNA Qualitative Real-Time RT-PCR Test

As described in Section IV below, Focus Diagnostics, Inc. is also authorized to make available additional information relating to the emergency use of the authorized Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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).

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 Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-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:

Focus Diagnostics, Inc.

A. Focus Diagnostics, Inc. will distribute the authorized Zika Virus RNA Qualitative Real-Time RT-PCR with the authorized labeling, as may be revised by Focus Diagnostics, Inc. in consultation with FDA, only to authorized laboratories.

B. Focus Diagnostics, Inc. will provide to authorized laboratories the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Health Care Providers, the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Pregnant Women, and the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact

Sheet for Patients.

C. Focus Diagnostics, Inc. will make available on its website the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Health Care Providers, the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Pregnant Women, and the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Patients.

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

E. Focus Diagnostics, Inc. will ensure that authorized laboratories using the authorized Zika Virus RNA Qualitative Real-Time RT-PCR have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.[5]

F. Focus Diagnostics, Inc. will track adverse events and report to FDA under 21 CFR Part 803, but can submit reports to FDA in paper form.

G. Through a process of inventory control, Focus Diagnostics, Inc. will maintain records of device usage.

H. Focus Diagnostics, Inc. will collect information on the performance of the test. Focus Diagnostics, Inc. 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 Focus Diagnostics, Inc. becomes aware.

I. Focus Diagnostics, Inc. is authorized to make available additional information relating to the emergency use of the authorized Zika Virus RNA Qualitative Real-Time RT-PCR that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Focus Diagnostics, Inc. may request changes to the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Health Care Providers, the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Pregnant Women, and the authorized Zika Virus RNA Qualitative Real-Time RT-PCR Fact Sheet for Patients. Such requests will be made by Focus Diagnostics, Inc. in consultation with FDA, and require concurrence of, FDA.

K. Focus Diagnostics, Inc. may request the addition of other real-time PCR instruments for use with the authorized Zika Virus RNA Qualitative Real-Time RT-PCR. Such requests will be made by Focus Diagnostics, Inc. in consultation with, and require concurrence of, FDA.

L. Focus Diagnostics, Inc. may request the addition of other extraction methods for use with the authorized Zika Virus RNA Qualitative Real-Time RT-PCR. Such requests will be made by Focus Diagnostics, Inc. in consultation with, and require concurrence of, FDA.

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

M. Focus Diagnostics, Inc. may request the addition of other specimen types for use with the authorized Zika Virus RNA Qualitative Real-Time RT-PCR. Such requests will be made by Focus Diagnostics, Inc. in consultation with, and require concurrence of, FDA.

N. Focus Diagnostics, Inc. will assess traceability[6] of the Zika Virus RNA Qualitative Real-Time RT-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, Focus Diagnostics, Inc. will update its labeling to reflect the additional testing.

Authorized Laboratories

O. Authorized laboratories will include with reports of the results of the Zika Virus RNA Qualitative Real-Time RT-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 Zika Virus RNA Qualitative Real-Time RT-PCR on the Applied Biosystems (ABI) 7500 Real-Time PCR Instrument or other authorized instruments.

Q. Authorized laboratories will have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.[7]

R. Authorized laboratories will collect information on the performance of the test and report to Focus Diagnostics, Inc., any suspected occurrence of false positive or false negative results of which they become aware.

S. 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.

Focus Diagnostics, Inc. and Authorized Laboratories

T. Focus Diagnostics, Inc. 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 Zika Virus RNA Qualitative Real-Time RT-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.

---

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

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

V. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika Virus RNA Qualitative Real-Time RT-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 of RNA from Zika 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 Zika Virus RNA Qualitative Real-Time RT-PCR may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Zika Virus RNA Qualitative Real-Time RT-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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

May 13, 2016

Dr. Sven Cramer
Director, Regulatory Affairs
altona Diagnostics GmbH
Mörkenstraβe 12
22767 Hamburg
Germany

Dear Dr. Cramer:

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 altona Diagnostics GmbH's RealStar® Zika Virus RT-PCR Kit U.S. for the qualitative detection of RNA from Zika virus in human serum and urine (collected alongside a patient-matched serum specimen) specimens 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 epidemiologic criteria for which Zika virus testing may be indicated), by laboratories in the United States 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] Assay results are for the identification of Zika viral RNA. Zika 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 exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection

[1] For ease of reference, this letter will refer to "laboratories in the United States 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] 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.

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 RealStar® Zika Virus RT-PCR Kit U.S. (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 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S., 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S. for detecting Zika virus and 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 epidemiologic criteria for which Zika virus testing may be indicated).

---

[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.

The Authorized RealStar® Zika Virus RT-PCR Kit U.S.

altona Diagnostics GmbH's RealStar® Zika Virus RT-PCR Kit U.S. is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of Zika virus RNA in serum and urine (collected alongside a patient-matched serum specimen) 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). The RealStar® Zika Virus RT-PCR Kit U.S. can also be used with other authorized specimen types. The test procedure consists of nucleic acid extraction using the Qiagen QIAamp® Viral RNA Mini kit, or other authorized extraction method, followed by rRT-PCR on the ABI Prism® 7500 SDS instrument, the ABI Prism® 7500 Fast SDS instrument, the LightCycler® 480 Instrument II, the CFX96™ Real-Time PCR Detection System, the CFX96™ Deep Well Real-Time PCR Detection System, the Rotor-Gene® 6000 instrument, the Rotor-Gene® Q 5/6 plex/MDx Platform or other authorized instruments.

The RealStar® Zika Virus RT-PCR Kit U.S. includes a primer and dual-labeled hydrolysis (Taqman®) probe set targeting a nucleotide sequence within the Zika virus genome to be used in the *in vitro* qualitative detection of Zika virus RNA isolated from human serum, urine and any other authorized specimens. The purified nucleic acids are first reverse transcribed into cDNAs. In the process, the probes anneal to the specific target sequences located between the respective forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating fluorescent signals. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity.

The RealStar® Zika Virus RT-PCR Kit U.S. includes the following materials:

- RealStar® Zika Virus RT-PCR Kit U.S. Primer and Probe sets for the detection of Zika virus and the Internal Control
  - Master A
  - Master B

The RealStar® Zika Virus RT-PCR Kit U.S. 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:

- RealStar® Zika Virus RT-PCR Kit U.S. Negative Control
  - PCR grade water
  - A negative control is included in each batch of specimen extractions to monitor Zika virus contamination

- RealStar® Zika Virus RT-PCR Kit U.S. Positive Control
  - Zika virus strain *in vitro* transcript which contains the target sequence used by the RealStar® Zika Virus RT-PCR Kit U.S.
  - A positive control is included in each batch of specimen extractions to

monitor nucleic acid isolation and detection of Zika virus RNA

- RealStar® Zika Virus RT-PCR Kit U.S. Internal Control
  - RNA target included in each specimen, Positive Control, and Negative Control
  - Consists of an artificial RNA molecule with no homologies to any other known sequences, added to the nucleic acid extraction procedure
  - Ensures the absence of non-specific PCR inhibition of a sample

The above described RealStar® Zika Virus RT-PCR Kit U.S., when labeled consistently with the labeling authorized by FDA entitled "RealStar® Zika Virus RT-PCR Kit U.S. Instructions for Use" (available at http://www.fda.gov/MedicalDevices/%20Safety/EmergencySituations/ucm161496.htm), which may be revised by altona Diagnostics GmbH 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S. Test Results
- Fact Sheet for Pregnant Women: Understanding Results from the RealStar® Zika Virus RT-PCR Kit U.S.
- Fact Sheet for Patients: Understanding Results from the RealStar® Zika Virus RT-PCR Kit U.S.

As described in Section IV below, altona Diagnostics GmbH is also authorized to make available additional information relating to the emergency use of the authorized RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S., 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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S. 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).

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 RealStar® Zika Virus RT-PCR Kit U.S. 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 RealStar® Zika Virus RT-PCR Kit U.S.

- 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:

altona Diagnostics GmbH and Its Authorized Distributor(s)

A. altona Diagnostics GmbH and its authorized distributor(s) will distribute the authorized RealStar® Zika Virus RT-PCR Kit U.S. with the authorized labeling, as may be revised by altona Diagnostics GmbH in consultation with FDA, only to authorized laboratories.

B. altona Diagnostics GmbH and its authorized distributor(s) will provide to authorized laboratories the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Health Care Providers, the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Pregnant Women, and the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Patients.

C. altona Diagnostics GmbH and its authorized distributor(s) will make available on their websites the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Health Care Providers, the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Pregnant Women, and the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Patients.

D. altona Diagnostics GmbH 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. altona Diagnostics GmbH and its authorized distributor(s) will ensure that authorized laboratories using the authorized RealStar® Zika Virus RT-PCR Kit U.S. have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.[5]

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

G. altona Diagnostics GmbH and its authorized distributor(s) will collect information on the performance of the test. altona Diagnostics GmbH 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 altona Diagnostics GmbH becomes aware.

H. altona Diagnostics GmbH and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized RealStar® Zika Virus RT-PCR Kit U.S. that is consistent with, and does not exceed, the terms of this letter of authorization.

altona Diagnostics GmbH

I. altona Diagnostics GmbH will notify FDA of any authorized distributor(s) of the RealStar® Zika Virus RT-PCR Kit U.S., including the name, address, and phone number of any authorized distributor(s).

J. altona Diagnostics GmbH 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

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

sheets, instructions for use).

K. altona Diagnostics GmbH may request changes to the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Health Care Providers, the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Pregnant Women, and the authorized RealStar® Zika Virus RT-PCR Kit U.S. Fact Sheet for Patients. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

L. altona Diagnostics GmbH may request the addition of other real-time PCR instruments for use with the authorized RealStar® Zika Virus RT-PCR Kit U.S. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

M. altona Diagnostics GmbH may request the addition of other extraction methods for use with the authorized RealStar® Zika Virus RT-PCR Kit U.S. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

N. altona Diagnostics GmbH may request the addition of other specimen types for use with the authorized RealStar® Zika Virus RT-PCR Kit U.S. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

O. altona Diagnostics GmbH will assess traceability[6] of the RealStar® Zika Virus RT-PCR Kit U.S. with a FDA-recommended reference material. After submission to FDA and FDA's review of and concurrence with the data, altona Diagnostics GmbH will update its labeling to reflect the additional testing.

P. altona Diagnostics GmbH will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

Q. Authorized laboratories will include with reports of the results of the RealStar® Zika Virus RT-PCR Kit U.S. 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.

R. Authorized laboratories will perform the RealStar® Zika Virus RT-PCR Kit U.S. on the ABI Prism® 7500 SDS instrument, the ABI Prism® 7500 Fast SDS instrument, the LightCycler® 480 Instrument II, the CFX96™ Real-Time PCR Detection System, the CFX96™ Deep Well Real-Time PCR Detection System, the Rotor-Gene® 6000 instrument, the Rotor-Gene® Q 5/6 plex/MDx Platform or other authorized instruments.

S. Authorized laboratories will have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.[7]

[6] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.
[7] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that altona Diagnostics GmbH and authorized laboratories consult with the applicable state or territory health department(s). According to CDC, Zika is a nationally notifiable condition. http://www.cdc.gov/zika/.

T. Authorized laboratories will collect information on the performance of the test and report to altona Diagnostics GmbH, any suspected occurrence of false positive or false negative results of which they become aware.

U. 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.

altona Diagnostics GmbH, Its Authorized Distributor(s) and Authorized Laboratories

V. altona Diagnostics GmbH, 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

W. All advertising and promotional descriptive printed matter relating to the use of the authorized RealStar® Zika Virus RT-PCR Kit U.S. 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.

X. All advertising and promotional descriptive printed matter relating to the use of the authorized RealStar® Zika Virus RT-PCR Kit U.S. 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, 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 RealStar® Zika Virus RT-PCR Kit U.S. may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized RealStar® Zika Virus RT-PCR Kit U.S. as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

Page 9 – Dr. Cramer, altona Diagnostics GmBH

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: June 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14380 Filed 6–16–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 16, 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–2007–D–0369 for ''Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry.'' 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 information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover