completion. We estimate that it will take an IRB approximately 1 hour to prepare a written statement to the study sponsor describing each public disclosure, for a total of 2 hours per study. The total annual third party disclosure burden for IRBs to fulfill this requirement related to emergency research under § 50.24 is estimated at 16 hours (see table 2).

When an IRB or institution violates the regulations, FDA issues to the IRB or institution a noncompliance letter (see § 56.120(a)). The IRB or institution must respond to the noncompliance letter describing the corrective actions that will be taken by the IRB or institution. FDA estimates about seven IRBs or institutions will be issued a noncompliance letter annually. We estimate that the IRB's or institution's response will take about 10 hours to prepare, with an estimated total annual burden of 70 hours.

In 2016, FDA disqualified one IRB under § 56.121. To date, no IRB or institution has been reinstated or applied for reinstatement under § 56.123. For this reason, we estimate the annual reporting burden for one respondent only. We estimate a 5-hour burden per response, with an estimated total annual burden of 5 hours.

The regulatory provisions in parts 50 and 56 currently approved under this collection of information, OMB control number 0910–0755, and for which this extension is requested, are shown in table 1.

In the **Federal Register** of July 19, 2016 (81 FR 46935), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.109(d) Written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	.5 (30 minutes)	2,520
56.109(e) IRB written notification to approve or disapprove research; 56.109(f) Continuing review; 50.25 Elements of informed consent; and 50.27 Documentation of informed consent.	2,520	40	100,800	1	100,800
50.24 Exception from informed consent requirements for emergency research.	8	3	24	1	24
56.113 Suspension or termination of IRB approval of research.	2,520	1	2,520	.5 (30 minutes)	1,260
56.120(a) IRB response to lesser administrative actions for noncompliance.	7	1	7	10	70
56.123 Reinstatement of an IRB or an institution	1	1	1	5	5
Total	.....	.....	.....	.....	104,679

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26528 Filed 11–2–16; 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 in vitro diagnostic devices for detection of the 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 Vela Diagnostics USA, Inc. and ARUP Laboratories. 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 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 Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Vela Diagnostics USA, Inc. is effective as of September 23, 2016; the Authorization for ARUP Laboratories is effective as of September 28, 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: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4336, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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

II. EUA Requests for In Vitro Diagnostic Devices 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

[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.

determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On September 1, 2016, Vela Diagnostics USA Inc., requested, and on September 23, 2016, FDA issued, an EUA for the *Sentosa* SA ZIKV RT–PCR Test, subject to the terms of the Authorization. On September 26, 2016, ARUP Laboratories requested, and on September 28, 2016, FDA issued an EUA for the Zika Virus Detection by RT–PCR test, 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) follows and provides an explanation of the reasons for 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

September 23, 2016

Donald Henton
Director Regulatory Affairs North America
Vela Diagnostics USA, Inc.
353C US Route 46 West, Suite 250
Fairfield, NJ 07004

Dear Mr. Henton:

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 Vela Diagnostics USA, Inc.'s ("Vela")[1] *Sentosa*® SA ZIKV RT-PCR Test 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).[2] 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,[3] 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, 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 U.S. citizens living abroad and that involves Zika virus.[4] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] At the time of authorization, Vela, as the EUA holder, is responsible for satisfying the Conditions of Authorization for the *Sentosa*® SA ZIKV RT-PCR Test, which is manufactured by Vela Operations (Singapore).
[2] 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."
[3] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on September 1, 2016).
[4] 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.

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).[5]

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 *Sentosa*® SA ZIKV 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 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 *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test, 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 *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test for detecting Zika virus and diagnosing Zika virus infection.[6]

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 *Sentosa*® SA ZIKV RT-PCR Test 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).

[5] 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).

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

The Authorized *Sentosa*® SA ZIKV RT-PCR Test

The *Sentosa*® SA ZIKV RT-PCR Test 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 plasma, urine (collected alongside a patient-matched serum or plasma specimen) and other authorized specimen types.

To perform the *Sentosa*® SA ZIKV RT-PCR Test, nucleic acids are isolated and purified from the sample using a magnetic bead based extraction method. Nucleic acid extraction is performed using the *Sentosa*® SX Virus Total Nucleic Acid Kit v2.0, or other authorized extraction methods. The Extraction Control is added to each sample prior to extraction.

Nucleic acid extraction and PCR set-up procedures are automated using the *Sentosa*® SX101 instrument, or other authorized instrument(s).

The purified nucleic acid is reverse transcribed into cDNA, which is then amplified. The ZIKV master mix, which contains reagents and enzymes for reverse transcription and specific amplification of the Zika virus targeted region, is added. This is followed by the detection of the target of interest on the Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument (ABI 7500 Fast Dx), the *Sentosa*® SA201, or other authorized instrument, for reverse transcription and PCR amplification.

The *Sentosa*® SA ZIKV RT-PCR Test uses the following materials, or other authorized materials or ancillary products:

- Enzyme Mix
- Zika Virus Primer/Probe Mix
- Extraction Control Primer/Probe Mix
- Extraction Control
- Positive Control
- Negative Control (nuclease free water)

The *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test Instructions for Use:

- Negative Control: Contains nuclease-free water. Controls for reagent and/or environmental contamination for the target channel and is used throughout the extraction and PCR set-up for each run.

- Positive Control: Contains *in vitro* transcribed Zika RNA. Monitors for substantial reagent failure and is used throughout the extraction and PCR set-up for each run.

- Extraction Control: Contains linearized plasmid DNA. 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 Instructions for Use.

The *Sentosa*® SA ZIKV RT-PCR Test also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized *Sentosa*® SA ZIKV RT-PCR Test Instructions for Use.

The above described *Sentosa*® SA ZIKV RT-PCR Test, when labeled consistently with the labeling authorized by FDA entitled "Instructions for Use: *Sentosa*® SA ZIKV RT-PCR Test and the Product Insert (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Vela 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 *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test Results
- Fact Sheet for Patients: Understanding Results from the *Sentosa*® SA ZIKV RT-PCR Test

As described in Section IV below, Vela and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized *Sentosa*® SA ZIKV RT-PCR Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test, 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 *Sentosa*® SA ZIKV RT-PCR Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the *Sentosa*® SA ZIKV RT-PCR Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Vela Diagnostics USA, Inc. and Its Authorized Distributor(s)

A. Vela and its authorized distributor(s) will distribute the authorized *Sentosa*® SA ZIKV RT-PCR Test with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. Vela and its authorized distributor(s) will provide to authorized laboratories the

authorized the *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Healthcare Providers and the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Patients.

C. Vela and its authorized distributor(s) will make available on their websites the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Healthcare Providers and the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Patients.

D. Vela 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. Vela and its authorized distributor(s) will ensure that the authorized laboratories using the authorized *Sentosa*® SA ZIKV RT-PCR Test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[7]

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

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

H. Vela and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized *Sentosa*® SA ZIKV RT-PCR Test that is consistent with, and does not exceed, the terms of this letter of authorization.

Vela Diagnostics USA, Inc.

I. Vela will notify FDA of any authorized distributor(s) of the *Sentosa*® SA ZIKV RT-PCR Test, including the name, address, and phone number of any, authorized distributor(s).

J. Vela 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. Vela may request changes to the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Healthcare Providers and the authorized *Sentosa*® SA ZIKV RT-PCR Test Fact Sheet for Patients. Such requests will be made by Vela 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 Vela, 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/).

L. Vela may request the addition of other instruments for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. Vela may request the addition of other extraction methods for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. Vela may request the addition of other specimen types for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. Vela may request the addition of other control materials for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. Vela may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized *Sentosa*® SA ZIKV RT-PCR Test. Such requests will be made by Vela in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. Vela will assess traceability[8] of the *Sentosa*® SA ZIKV RT-PCR Test with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Vela will update its labeling to reflect the additional testing.

R. Vela, assuming the medical device reporting responsibilities of the manufacturer of the *Sentosa*® SA ZIKV RT-PCR Test, 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 *Sentosa*® SA ZIKV RT-PCR Test 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 *Sentosa*® SA ZIKV RT-PCR Test on the Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument, the *Sentosa*® SA201 instrument, or other authorized instruments.

U. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test using nucleic acid extraction and PCR set-up procedures automated by the *Sentosa*® SX101 instrument, or other authorized instruments.

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

V. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test using the *Sentosa*® SX Virus Total Nucleic Acid Kit v2.0 for nucleic acid extraction, or with other authorized extraction methods.

W. Authorized laboratories will perform the *Sentosa*® SA ZIKV RT-PCR Test on human serum, EDTA plasma, or urine (collected alongside a patient-matched serum or plasma specimen) or with other authorized specimen types.

X. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[9]

Y. Authorized laboratories will collect information on the performance of the test and report to Vela 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.

Vela Diagnostics USA, Inc., Its Authorized Distributor(s) and Authorized Laboratories

AA. Vela, 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 *Sentosa*® SA ZIKV RT-PCR Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

CC. All advertising and promotional descriptive printed matter relating to the use of the authorized *Sentosa*® SA ZIKV RT-PCR Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by 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

[9] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Vela, 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/.

- 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 *Sentosa®* SA ZIKV RT-PCR Test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized *Sentosa®* SA ZIKV RT-PCR Test 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

September 28, 2016

Dr. Jerry Hussong
Chief Medical Officer, Director of Labs
ARUP Laboratories
Mail Code 209-D02
500 Chipeta Way
Salt Lake City, UT 84108

Dear Dr. Hussong:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the ARUP Laboratories' Zika Virus Detection by RT-PCR test for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma and urine (collected alongside a patient-matched serum or EDTA 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). Testing is limited to laboratories designated by ARUP Laboratories[1] that are 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).[2] 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,[3] 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, 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 U.S. citizens living abroad and that involves Zika virus.[4] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] At the time of authorization, ARUP Laboratories in Salt Lake City, Utah is the only designated laboratory.
[2] For ease of reference, this letter will refer to "laboratories designated by ARUP Laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests," as "authorized laboratories."
[3] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on September 1, 2016).
[4] 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 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).[5]

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 Detection by 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 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 Zika Virus Detection by RT-PCR test 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 Detection by RT-PCR test, 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 Zika Virus Detection by RT-PCR test 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 Detection by RT-PCR test for detecting Zika virus and diagnosing Zika virus infection.[6]

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 Detection by RT-PCR test 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.,

[5] 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).

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

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 Zika Virus Detection by RT-PCR test

The ARUP Laboratories' Zika Virus Detection by RT-PCR test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, urine (collected alongside a patient-matched serum or EDTA plasma specimen) and other authorized specimen types.

To perform the Zika Virus Detection by RT-PCR test, specimens are first extracted to isolate the Zika virus RNA. Nucleic acids are isolated and purified from the sample using the chemagic MSM I extraction platform (Perkin Elmer) with the protocol for total nucleic acid extraction, or other authorized extraction methods.

The purified nucleic acid is reverse transcribed into cDNA and amplified using a 2X custom Multiplex 1-step RT-qPCR master mix (Quanta Bioscience), which contains reagents and enzymes for reverse transcription and specific amplification of the Zika virus region. In the amplification process, the probe anneals to the specific target sequence located between the forward and reverse primers generating a fluorescent signal. With each cycle, additional amplicon is produced, increasing the amount of annealed probe and subsequent fluorescence signal. The RT-PCR is performed on the QuantStudio 12K Flex real-time PCR instrument (Thermo Fisher), or other authorized instruments.

The Zika Virus Detection by RT-PCR test uses the following materials, or other authorized materials or ancillary products:

- Zika Virus Enzyme Mix
- Zika Virus Primer/Probe Mix
- Zika Virus Internal Control
- Zika Virus Negative Extraction Control
- Zika Virus Positive Extraction Control
- No Template Control (nuclease free water)

The Zika Virus Detection by RT-PCR test 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 Zika Virus Detection by RT-PCR, ARUP Laboratories, Instructions for Use:

- Zika Virus Internal Control
  - The internal control consists of a bacteriophage MS2 that is added to each specimen prior to extraction, is co-purified with each specimen, and is amplified by a specific primers and probe set.
  - The internal control MS2 controls for sample extraction, reverse transcription, amplification and detection and also ensures the absence of non-specific PCR inhibition of a sample.

- No Template Control

- RNase, DNase-free water.
- A no template control is included in each RT-PCR run of specimen extractions to monitor for Zika virus contamination.

- Zika Virus Negative Extraction Control
  - Known negative sample.
  - A negative extraction control is included in each run of specimen extractions to monitor for Zika virus contamination.

- Zika Virus Positive Extraction Control
  - Live Zika whole virus.
  - A positive control is included in each run of specimen extractions to monitor nucleic acid isolation and detection of Zika virus RNA.

The above described Zika Virus Detection by RT-PCR test, when labeled consistently with the labeling authorized by FDA entitled "Zika Virus Detection by RT-PCR, ARUP Laboratories, Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by ARUP Laboratories 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 Zika Virus Detection by RT-PCR test 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 Zika Virus Detection by RT-PCR Test Results
- Fact Sheet for Patients: Understanding Results from the Zika Virus Detection by RT-PCR Test

As described in Section IV below, ARUP Laboratories, and other authorized distributer(s), are also authorized to make available additional information relating to the emergency use of the authorized Zika Virus Detection by RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Zika Virus Detection by RT-PCR test 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 Detection by RT-PCR test 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 Detection by RT-PCR test, 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 Detection by RT-PCR test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Zika Virus Detection by RT-PCR test 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 transmission 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 Zika Virus Detection by RT-PCR test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Zika Virus Detection by RT-PCR test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

ARUP Laboratories and/or Other Authorized Distributor(s)

A. ARUP Laboratories and other authorized distributor(s) will distribute the authorized Zika Virus Detection by RT-PCR test with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. ARUP Laboratories and other authorized distributor(s) will provide to authorized laboratories the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Healthcare Providers and the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Patients.

C. ARUP Laboratories and other authorized distributor(s) will make available on their websites the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Healthcare Providers and the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Patients.

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

E. ARUP Laboratories and other authorized distributor(s) will ensure that the authorized laboratories using the authorized Zika Virus Detection by RT-PCR test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[7]

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

G. ARUP Laboratories and other authorized distributor(s) will collect information on the performance of the test. ARUP Laboratories 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 ARUP Laboratories becomes aware.

H. ARUP Laboratories and other authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Zika Virus Detection by RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

ARUP Laboratories

I. ARUP Laboratories will notify FDA of any authorized distributor(s) of the Zika Virus Detection by RT-PCR test, including the name, address, and phone number of any authorized distributor(s).

J. ARUP Laboratories will provide other authorized distributor(s) with a copy of this

[7] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that ARUP Laboratories, authorized distributors, 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/.

EUA, and communicate to other authorized distributor(s) any subsequent amendments that might be made to this EUA and other authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. ARUP Laboratories may request changes to the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Healthcare Providers and the authorized Zika Virus Detection by RT-PCR test Fact Sheet for Patients. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. ARUP Laboratories may request the addition of other instruments for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. ARUP Laboratories may request the addition of other extraction methods for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. ARUP Laboratories may request the addition of other specimen types for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. ARUP Laboratories may request the addition of other control materials for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. ARUP Laboratories may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Zika Virus Detection by RT-PCR test. Such requests will be made by ARUP Laboratories in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. ARUP Laboratories will assess traceability[$] of the Zika Virus Detection by RT-PCR test with FDA recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, ARUP Laboratories will update its labeling to reflect the additional testing.

R. ARUP Laboratories 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 Zika Virus Detection by RT-PCR test 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.

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

T. Authorized laboratories will perform the Zika Virus Detection by RT-PCR test on the QuantStudio 12K Flex real-time PCR instrument (Thermo Fisher), or other authorized instruments.

U. Authorized laboratories will perform the Zika Virus Detection by RT-PCR test using the chemagic MSM I extraction platform (Perkin Elmer) with the protocol for total nucleic acid extraction, or with other authorized extraction methods.

V. Authorized laboratories will perform the Zika Virus Detection by RT-PCR test on human serum, EDTA plasma, or urine (collected with a patient-matched serum or EDTA plasma specimen) or with other authorized specimen types.

W. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[9]

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

Y. 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.

ARUP Laboratories, Other Authorized Distributor(s) and Authorized Laboratories

Z. ARUP Laboratories, other 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

AA. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika Virus Detection by RT-PCR test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika Virus Detection by RT-PCR test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;

[9] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that ARUP Laboratories, authorized distributors, 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 – Dr. Hussong, ARUP 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.

No advertising or promotional descriptive printed matter relating to the use of the authorized Zika Virus Detection by RT-PCR test 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 Detection by RT-PCR test 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: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26532 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

DATES: Submit either electronic or written comments on the collection of information by January 3, 2017.

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.''