default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On February 23, 2017, the committee will discuss and make recommendations on clinical information related to the *de novo* request for the Sentinel® Cerebral Protection System, a first of a kind embolic protection device to be used with transcatheter aortic valve replacement (TAVR) procedures.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 9, 2017. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 1, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 2, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 4, 2017.

Janice M. Soreth,

Associate Commissioner, Special Medical Programs.

[FR Doc. 2017–00143 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4586]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by ELITechGroup Inc. Molecular Diagnostics. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of December 9, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

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

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a

determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

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

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

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

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

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On November 28, 2016, ELITechGroup Inc. Molecular Diagnostics requested, and on December 9, 2016, FDA issued, an EUA for the Zika ELITe MGB® 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 Authorization are available on the Internet at *https://www.regulations.gov/*.

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of Zika virus subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

December 9, 2016

Terry Trimingham
Senior Regulatory Affairs Specialist
ELITechGroup Inc. Molecular Diagnostics
21720 23rd Drive SE, Suite 150
Bothell, WA 98021

Dear Mr. Trimingham:

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 ELITechGroup Inc. Molecular Diagnostics' ("EGI MDx") Zika ELITe MGB® Kit U.S. for the qualitative detection of RNA from Zika virus in human serum and EDTA plasma from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[2] up to 14 days in serum, 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.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

[1] For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."
[2] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on November 16, 2016).
[3] As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of significant potential for a public health emergency.
[4] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika 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 ELITe MGB® 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 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 ELITe MGB® 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 Zika ELITe MGB® Kit U.S., 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 ELITe MGB® 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 Zika ELITe MGB® Kit U.S. for detecting Zika virus and diagnosing Zika virus infection.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Zika ELITe MGB® 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 epidemiological criteria for which Zika virus testing may be indicated).

The Authorized Zika ELITe MGB® Kit U.S.

The Zika ELITe MGB® Kit U.S. 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

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

plasma and other authorized specimen types. The Zika ELITe MGB® Kit U.S. uses a primer set and single uniquely labeled probe to amplify and detect the NS3 protein encoding gene of Zika virus.

The Zika ELITe MGB® Kit U.S. is performed using the ELITe InGenius™ instrument or other authorized instruments. The ELITe InGenius™ instrument automates the nucleic acid extraction, amplification and detection. The RNA is extracted and purified from the patient specimen before it is reverse transcribed into cDNA which is then amplified using the primer set and detected using the specific probe.

The Zika ELITe MGB® Kit U.S. includes the following materials or other authorized materials: 20x Zika PreMix, PCR MasterMix, RT EnzymeMix, PCR Grade Water, Negative Control, MS2 RNA Internal Control, Zika – Positive Control. The Zika ELITe MGB® Kit U.S. also requires the use of additional materials and ancillary reagents that are not include with the test but are commonly used in clinical laboratories and are described in the authorized Zika ELITe MGB® Kit U.S. Instructions for Use.

The Zika ELITe MGB® Kit U.S. requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Zika ELITe MGB® Kit U.S. Instructions for Use:

- Zika - Positive Control: Synthetic Zika RNA stabilized in a guanidinium buffer, requires extraction – run in place of a sample daily. Monitors for failures of rRT-PCR reagents and reaction conditions.
- Negative Control: DNase and RNase-free water – run in place of a sample on every batch run. Monitors for reagent and system contamination.
- MS2 RNA Internal Control: MS2 RNA stabilized in a guanidinium buffer, requires extraction – added automatically to each sample and control during the extraction step. The MS2 RNA is co-extracted and co-amplified with the target nucleic acid, and monitors for integrity of the kit reagents, equipment function and the presence of amplification inhibitors in the samples.

The above described Zika ELITe MGB® Kit U.S., when labeled consistently with the labeling authorized by FDA entitled "Zika ELITe MGB® Kit U.S." (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by EGI MDx 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 ELITe MGB® 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 healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting Zika ELITe MGB® Kit U.S. Test Results
- Fact Sheet for Patients: Understanding Results from the Zika ELITe MGB® Kit U.S.

As described in Section IV below, EGI MDx and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized Zika ELITe MGB® 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 Zika ELITe MGB® 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 Zika ELITe MGB® 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 Zika ELITe MGB® 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 Zika ELITe MGB® 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 Zika ELITe MGB® 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 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 Zika ELITe MGB® 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 Zika ELITe MGB® 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:

ELITechGroup Inc. Molecular Diagnostics and Its Authorized Distributor(s)

A. EGI MDx and its authorized distributor(s) will distribute the authorized Zika ELITe MGB® Kit U.S. with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. EGI MDx and its authorized distributor(s) will provide to authorized laboratories the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Healthcare Providers and the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Patients.

C. EGI MDx and its authorized distributor(s) will make available on their websites the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Healthcare Providers and the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Patients.

D. EGI MDx 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. EGI MDx and its authorized distributor(s) will ensure that the authorized laboratories using the authorized Zika ELITe MGB® Kit U.S. have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[6]

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

[6] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that EGI MDx, 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/).

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

H. EGI MDx and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Zika ELITe MGB® Kit U.S. that is consistent with, and does not exceed, the terms of this letter of authorization.

ELITechGroup Inc. Molecular Diagnostics

I. EGI MDx will notify FDA of any authorized distributor(s) of the Zika ELITe MGB® Kit U.S., including the name, address, and phone number of any authorized distributor(s).

J. EGI MDx 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. EGI MDx may request changes to the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Healthcare Providers and the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Patients. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. EGI MDx may request the addition of other instruments for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. EGI MDx may request the addition of other extraction methods for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. EGI MDx may request the addition of other specimen types for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. EGI MDx may request the addition and/or substitution of other control materials for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. EGI MDx may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. EGI MDx will assess traceability[7] of the Zika ELITe MGB® Kit U.S. with FDA-

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

recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, EGI MDx will update its labeling to reflect the additional testing.

R. EGI MDx 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 ELITe MGB® Kit U.S. 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 Zika ELITe MGB® Kit U.S. on the ELITe InGenius™ instrument, or other authorized instruments.

U. Authorized laboratories will perform the Zika ELITe MGB® Kit U.S. on human serum, EDTA plasma, or other authorized specimen types.

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

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

X. 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.

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

Y. EGI MDx, 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

Z. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika ELITe MGB® 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.

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

Page 8 – Mr. Terry Trimingham, ELITechGroup Inc. Molecular Diagnostics, USA

AA. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika ELITe MGB® 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, 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 ELITe MGB® 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 Zika ELITe MGB® Kit U.S. 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: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00084 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–1196 and FDA–2016–E–1197]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 10, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for