Page 15 – Dr. Schuchat, CDC

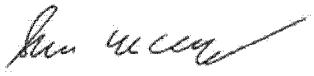
the initial treatment of muscarinic symptoms of poisoning by susceptible nerve agents or certain insecticides (organophosphorus and/or carbamate).

The emergency use of the authorized Rafa Atropine Auto-Injector 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 injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

Dated: June 26, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13664 Filed 6–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0523]

Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug

Correction

In notice document 2017–10818 appearing on pages 24351 through 24356 in the issue of Friday, May 26, make the following correction:

On page 24351, in the third column, under the **DATES** heading, in the third line ''June 26, 2017'' should read ''July 25, 2017''.

[FR Doc. C1–2017–10818 Filed 6–29–17; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0969]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Roche Molecular Systems, Inc. for the *LightMix® Zika rRT–PCR Test.* FDA revoked this Authorization on March 13, 2017, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Roche Molecular Systems, Inc. by letter dated March 10, 2017. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of March 13, 2017.

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

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. On August 26, 2016, FDA issued an EUA to Roche Molecular Systems, Inc. for the *LightMix® Zika rRT–PCR Test,* subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on October 28, 2016 (81 FR 75092), as required by section 564(h)(1) of the FD&C Act. Under section 564(g)(2), the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no

longer met or other circumstances make such revocation appropriate to protect the public health or safety.

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

On March 10, 2017, Roche Molecular Systems, Inc. requested, and on March 13, 2017, FDA revoked, the EUA for the *LightMix® Zika rRT–PCR* Test because the criteria for issuance were no longer met and other circumstances made such revocation appropriate to protect the public health or safety.

II. Electronic Access

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

III. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Roche Molecular Systems, Inc.'s *LightMix® Zika rRT–PCR Test.* The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 13, 2017

Angela Tucker, Ph.D.
Vice President, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Dear Dr. Tucker:

This letter is in response to your request dated March 10, 2017, that the Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA160017) for emergency use of Roche Molecular Systems, Inc.'s ("Roche") *LightMix® Zika rRT-PCR Test* issued on August 26, 2016, and amended on November 23, 2016. Roche has decided to no longer market the product.

Under section 564(g)(2) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 360bbb-3(g)(2), FDA has determined that the criteria for authorization under section 564(c) of the Act are no longer met. The known and potential benefits of the test for detecting Zika virus and diagnosing Zika virus infection no longer outweigh the known and potential risk of the product due to concerns regarding the false positive results observed. In addition, the product will no longer be marketed and these circumstances make revocation appropriate to protect the public health or safety.

Accordingly, FDA revokes the EUA for emergency use of the *LightMix® Zika rRT-PCR Test*, under section 564(g) of the Act. As of the date of this letter, the *LightMix® Zika rRT-PCR Test* that was authorized by FDA for use by clinical laboratories for the qualitative detection of RNA from Zika virus is no longer authorized by FDA.

FDA encourages Roche to instruct laboratories to discontinue use of and discard any remaining inventory immediately.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564 of the Act, 21 U.S.C. 360bbb-3.

Sincerely,

Stephen Ostroff, M.D.
Acting Commissioner of Food and Drugs

Dated: June 21, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13666 Filed 6–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–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 Nanobiosym Diagnostics, Inc. and DiaSorin Inc. 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 Nanobiosym Diagnostics, Inc. is effective as of March 20, 2017; the Authorization for DiaSorin Inc. is effective as of April 5, 2017.

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

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (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