4164-01-P

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.

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