

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.

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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".

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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