4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis 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 Luminex Corp., for the xMAP MultiFLEX Zika RNA Assay. FDA revoked this Authorization on July 3, 2019, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by Luminex Corp. by a letter dated June 18, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of July 3, 2019.

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: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (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 4, 2016, FDA issued an EUA to Luminex Corp. for the xMAP MultiFLEX Zika RNA Assay, 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. In response to requests from Luminex Corp., the EUA was amended on January 7, 2017, and May 19, 2017. Under section 564(g)(2) of the FD&C Act, the Secretary of HHS 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 June 18, 2019, Luminex Corp. requested, and on July 3, 2019, FDA revoked, the EUA for the xMAP MultiFLEX Zika RNA Assay because the product will no longer be marketed, and these circumstances make revocation appropriate to protect the public health or safety.

III. 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/.

IV. 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 Luminex Corp.'s xMAP MultiFLEX Zika RNA Assay. 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.

July 3, 2019

Ronald Dunn
Vice President Global Regulatory and Clinical Affairs
Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727

Dear Mr. Dunn:

This letter is in response to Luminex Corporation's ("Luminex's") request dated June 18, 2019, that the Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA160015) for emergency use of the xMAP MultiFLEX Zika RNA Assay issued on August 4, 2016, and amended on January 7, 2017, and May 19, 2017. Luminex has decided to discontinue manufacture of the product and indicated that there are currently no lots of product in the field, all inventory is expired and Luminex will not manufacture additional lots.

Accordingly, FDA revokes EUA160015 for emergency use of the xMAP MultiFLEX Zika RNA Assay, under section 564(g)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3(g)(2)). The product will no longer be marketed, and these circumstances make revocation appropriate to protect the public health or safety. As of the date of this letter, the xMAP MultiFLEX Zika RNA Assay 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 Luminex 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(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: September 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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