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 Chembio Diagnostic Systems, Inc. ("Chembio") for the DPP Zika IgM Assay System. FDA revoked this Authorization on June 3, 2020, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), in consideration of the premarket notification clearance by FDA for the DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader that was determined to be substantially equivalent to a legally marketed class II predicate device on June 3, 2020. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of June 3, 2020.

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.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) 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 September 27, 2017, FDA issued an EUA to Chembio, for the DPP Zika IgM Assay System, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the *Federal Register* on November 17, 2017 (82 FR 54361), as required by section 564(h)(1) of the FD&C Act. In response to requests from Chembio, the EUA was amended on February 6, 2018, and August 3, 2018. Subsequently, on June 3, 2020, Chembio submitted a premarket notification to FDA for the DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader (K200506), that was determined to be substantially equivalent to a legally marketed Class II predicate device.

II. EUA Criteria for Issuance No Longer Met

Under section 564(g)(2) of the FD&C Act, the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met. On June 3, 2020, FDA revoked the EUA for Chembio's DPP Zika IgM Assay System because the criteria

for issuance were no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. FDA has determined that the criteria for issuance of such authorization under section 564(c)(3) of the FD&C Act are no longer met because Chembio's DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader was determined on June 3, 2020, to be substantially equivalent to a legally marketed class II predicate device with the generic name "Zika virus serological reagents." As such, FDA concluded that there is an adequate, approved, and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the FD&C Act and accordingly revoked the Authorization pursuant to section 564(g)(2)(B) of the FD&C Act.

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 Chembio's DPP Zika IgM Assay System. 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.

U.S. FOOD & DRUG ADMINISTRATION

June 3, 2020

Louise Muscat Sigismondi
R&D Director of Regulatory Affairs
Chembio Diagnostic Systems
3661 Horseblock Road
Medford, NY 11763

Dear Ms. Sigismondi:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA170006) for emergency use of Chembio Diagnostic Systems, Inc.'s ("Chembio") DPP Zika IgM Assay System, issued on September 27, 2017, and amended on February 6, 2018, and August 3, 2018.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved[1], and available alternative to the product for diagnosing, preventing, or treating the disease or condition. Chembio submitted a premarket notification to FDA for the DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader (K200506) that was determined to be substantially equivalent to a legally marketed Class II predicate device, classified under 21 CFR 866.3935, with the generic name "Zika virus serological reagents," on June 3, 2020. FDA has concluded "that this is an adequate, approved[1], and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the Act."

Accordingly, FDA revokes EUA170006 for emergency use of DPP Zika IgM Assay System, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the DPP Zika IgM Assay System that was authorized by FDA for emergency use under EUA170006 is no longer authorized by FDA.

[1] In the context of section 564, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

Chembio should instruct customers who have remaining DPP Zika IgM Assay System EUA product inventory to work with Chembio to replace the EUA product with the device cleared under K200506. FDA encourages Chembio to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the device cleared on June 3, 2020, under premarket notification submission K200506.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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