the United States; principals in violation of 18 U.S.C. 545 and 2(b).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: As contained in count 1 of the information in Mr. Lee's case, filed on January 7, 2019, to which Mr. Lee pleaded guilty, between 2011 and 2017 Mr. Lee owned, controlled, and operated four businesses for the purpose of manufacturing and distributing male sexual enhancement pills that he marketed as herbal remedies but that contained undisclosed tadalafil, a prescription drug product. Until February 22, 2017, Mr. Lee conspired with others to import bulk tadalafil, with labeling that was false and misleading, from suppliers in China contrary to law. Mr. Lee had his Chinese suppliers ship the bulk tadalafil under false labeling to commercial mailboxes that he controlled in New Jersey and Pennsylvania. Mr. Lee then had the commercial mailbox companies that received the Chinese shipment repackage the tadalafil shipments and forward them to mailboxes Mr. Lee controlled in California. After receiving the bulk tadalafil in California, Mr. Lee caused it to be manufactured into at least 5 and a half million pills that he sold to distributors across the United States. The pills Mr. Lee manufactured contained levels of tadalafil significantly higher than the levels in FDA-approved prescription drugs such as Cialis. Mr. Lee sold at least $11 million worth of these pills to distributors in packages with labeling that did not disclose the presence of tadalafil. When, as on a number of occasions, FDA announced that a brand of pills sold by one of Mr. Lee companies contained undeclared tadalafil, he would establish a new company and/or begin manufacturing identical pills with different brand names in an effort to evade FDA regulators.

As contained in count 2 of the information in Mr. Lee's case, to which Mr. Lee pleaded guilty, on or about February 9, 2017, Mr. Lee fraudulently and knowingly, and contrary to law, imported two parcels of the bulk drug tadalafil with labeling that was false and misleading as to the parcels' contents, labels that did not contain accurate statements of the quantity of the contents in terms of weight, measure, and numerical count, and labeling that did not bear adequate directions for use, contrary to sections 301(a) and 502(a)(1), (b), and (f) of the FD&C Act (21 U.S.C. 331(a), 352(a)(1), (b), and (f)).

As a result of these convictions, FDA sent Mr. Lee, by certified mail on February 10, 2020, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Lee's felony conviction for one felony count under Federal law for conspiracy to import merchandise contrary to law and to defraud the United States was for conduct relating to the importation into the United States of any drug or controlled substance because he conspired to illegally import bulk tadalafil and repackage it into pills that he resold across the United States. The proposal was also based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Lee's felony conviction for one felony count under Federal law for importing merchandise contrary to law was for conduct relating to the importation into the United States of any drug or controlled substance because he also fraudulently and knowingly imported two parcels of bulk drug tadalafil into the United States contrary to sections 301(a) and 502(a)(1), (b), and (f) of the FD&C Act.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Lee's offenses, and concluded that these felony offenses warrant the imposition of a 10-year period of debarment.

The proposal informed Mr. Lee of the proposed debarment and offered Mr. Lee an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Lee received the proposal and notice of opportunity for a hearing on February 14, 2020. Mr. Lee failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. John Seil Lee has been convicted of two felony counts under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that each offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act. Under section 306(c)(2)(A) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA may determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 5-year period of debarment for each of the two offenses for which Mr. Lee was convicted will run consecutively, resulting in a total debarment period of 10 years.

As a result of the foregoing finding, Mr. Lee is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Lee is a prohibited act.

Any application by Mr. Lee for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–5969 and sent to the Dockets Management Staff (see **ADDRESSSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16062 Filed 7–23–20; 8:45 am]

BILLING CODE 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.

BILLING CODE 4164–01–P

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.

Page 2 – Ms. Sigismondi, Chembio Diagnostic Systems.

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.

[FR Doc. 2020–16014 Filed 7–23–20; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Prasadarao Nemani, Ph.D. (also known as Nemani V. Prasadarao) (Respondent), Research Professor of Pediatrics, Division of Infectious Disease, Children's Hospital Los Angeles (CHLA). Dr. Nemani engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI040567 and R01 AI049473. The administrative actions, including supervision for a period of four (4) years, were implemented beginning on July 7, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case: *Prasadarao Nemani, Ph.D., Children's Hospital Los Angeles:* Based on the report of an investigation conducted by CHLA and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Prasadarao Nemani, Research Professor of Pediatrics, Division of Infectious Disease, CHLA, engaged in research misconduct in research supported by PHS funds, specifically NIAID, NIH, grants R01 AI040567 and R01 AI049473.

ORI found that Respondent engaged in research misconduct by recklessly including falsified and/or fabricated data in the following published paper and grant applications submitted for PHS funds:

- *Infect Immun.* 2009;77:1031–43 (hereafter referred to as ''*Infect Immun* 2009''). Retraction in: *Infect Immun.* 2018 May 22;86(6):e00212–18
- R01 AI107015–01 submitted to NIAID, NIH
- R01 AI125595–01A1 submitted to NIAID, NIH
- R01 AI125595–01 submitted to NIAID, NIH
- R01 NS073115–06A1 submitted to the National Institute of Neurological Disorders and Stroke (NINDS), NIH

Respondent recklessly reported falsified and/or fabricated image data for enterobacterial infection-induced intestinal epithelial cell injury in a neonatal murine model to falsely represent results using images from unrelated experiments in eight (8) figures included in one (1) published paper and four (4) grant applications. Specifically, Respondent falsely reported the following figures:

- Figure 1C in *Infect Immun* 2009
- Figures 7, 8A, 8B, and 8C in R01 AI107015–01
- Figure 6C in R01 AI125595–01A1
- Figure 6C R01 AI125595–01
- Figure 5B in R01 NS073115–06A1

Dr. Nemani entered into a Voluntary Settlement Agreement and agreed to the following:

(1) Respondent agreed to have his research supervised for a period of four (4) years beginning on July 7, 2020. Respondent agreed that prior to the