systems, population, analytes) for the types of assessments discussed in item (1)(b)(i) above? Please describe the rationale for any design considerations proposed.

(2) Evaluating the Pharmacokinetics in Organ Impairment

(a) Under what circumstances are organ impairment assessments for oligonucleotide therapeutics warranted or not warranted for:

(i) Renal function

(ii) hepatic function

(b) In circumstances where organ impairment assessments are warranted:

(i) What types of assessments are suitable for renal and/or hepatic impairment and why (*e.g.,* dedicated clinical studies, population pharmacokinetic analyses)? Please discuss the advantages, challenges, and limitations with each type of assessment.

(ii) What are the study design considerations (*e.g.,* study population) for the types of assessments discussed in item (2)(b)(i) above for renal and/or hepatic impairment? Please describe the rationale for any design considerations proposed.

(3) Evaluating Immunogenicity

(a) Under what circumstances are immunogenicity assessments of oligonucleotide therapeutics warranted or not warranted?

(b) In circumstances where immunogenicity assessments are warranted:

What types of assessments are suitable and why (*e.g.,* antibodies against other components of the formulation, antibodies against a newly created ''splice-altered'' protein, neutralizing titers, cytokine measurements)? Please discuss the advantages, challenges, and limitations with each type of assessment.

(4) Evaluating QT Prolongation

(a) Under what circumstances are cardiac electrophysiology assessments warranted or not warranted in the evaluation of oligonucleotide therapeutics?

(b) In circumstances where cardiac electrophysiology assessments are warranted:

What types of assessments are suitable and why (*e.g.,* hERG inhibition assay, thorough QT assessment) in nonclinical or clinical studies? Please discuss the advantages, challenges, and limitations with each type of assessment.

(5) With regard to the four questions above, when a sponsor seeks to rely on previously generated data and information that it owns or to which it has a right of reference, what scientific findings may be applied across the sponsor's oligonucleotide therapeutics with shared characteristics (*e.g.,* similar backbone modifications)?

FDA will consider all information and comments submitted.

III. Electronic Access

Persons with access to the internet may obtain relevant clinical pharmacology guidances at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: August 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16880 Filed 8–6–19; 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 InBios International, Inc. (InBios), for the ZIKV Detect 2.0 IgM Capture ELISA. FDA revoked this Authorization on May 23, 2019, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in consideration of the De Novo classification request granted to the InBios ZIKV Detect 2.0 IgM Capture ELISA as a Class II device under the generic name Zika virus serological reagents on May 23, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of May 23, 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 17, 2016, FDA issued an EUA to InBios for the ZIKV Detect 2.0 IgM Capture ELISA, 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 InBios, the EUA was amended on March 27, 2017, and May 18, 2018. Under section 564(g)(2) of the FD&C Act, the Secretary of Health and Human Services (HHS) may revoke an EUA if, among other things, the criteria for issuance are no longer met.

II. EUA Criteria for Issuance No Longer Met

On March 23, 2019, FDA revoked the EUA for the InBios ZIKV Detect 2.0 IgM Capture ELISA 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. The InBios ZIKV Detect 2.0 IgM Capture ELISA had a De Novo classification request granted as a Class II device under the generic name Zika virus serological reagents on May 23, 2019 (*https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf*). FDA has concluded that this is an adequate, approved, and available alternative for diagnosing Zika virus infection.

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 the InBios ZIKV Detect 2.0 IgM Capture ELISA. 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

May 23, 2019

Estela Raychaudhuri
President
InBios International, Inc.
562 1st Avenue S., Suite 600
Seattle, WA 98104

Dear Ms. Raychaudhuri:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA160013) for emergency use of InBios International, Inc.'s ("InBios") ZIKV Detect 2.0 IgM Capture ELISA, issued on August 17, 2016, and amended on March 27, 2017, and May 18, 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, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. The InBios ZIKV Detect 2.0 IgM Capture ELISA had a De Novo classification request granted as a Class II device under the generic name Zika virus serological reagents in 21 CFR 866.3935 on May 23, 2019 (https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf). FDA has concluded that this is an adequate, approved, and available alternative for diagnosing Zika virus infection.

Accordingly, FDA revokes EUA160013 for emergency use of ZIKV Detect 2.0 IgM Capture ELISA, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the ZIKV Detect 2.0 IgM Capture ELISA test that was authorized by FDA for emergency use under EUA 160013 is no longer authorized by FDA.

FDA does not have concerns with the use of any remaining inventory of the ZIKV Detect 2.0 IgM Capture ELISA that was distributed prior to revocation of the EUA, when such product is used in conjunction with the ZIKV Detect 2.0 IgM Capture ELISA package insert/manufacturer instructions for use associated with the De Novo request granted May 23, 2019. FDA encourages the relabeling of any product already manufactured but not distributed prior to the revocation of the EUA with the ZIKV Detect 2.0 IgM Capture ELISA package

Page 2 – Ms. Raychaudhuri, InBios International, Inc.

insert/manufacturer instructions for use associated with the De Novo request granted May 23, 2019. Importantly, the ZIKV Detect 2.0 IgM Capture ELISA product for which FDA had issued an EUA and the product for which FDA has granted De Novo classification are manufactured under the same quality system with the same lot release criteria. InBios should instruct customers who have remaining ZIKV Detect 2.0 IgM Capture ELISA EUA product inventory to use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the De Novo request granted May 23, 2019. FDA encourages InBios 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 package insert/manufacturer instructions for use labeling associated with the De Novo request granted May 23, 2019.

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: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16881 Filed 8–6–19; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products.

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: