Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16889 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–2832]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nomination for Nonvoting Industry Representatives on the Vaccines and Related Biological Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the VRBPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by *September 6, 2019,* (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by September 6, 2019.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, Fax: 301–595–1307, Serina.Hunter-Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. CBER Advisory Committee

Vaccines and Related Biological Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which FDA has regulatory responsibility. The committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs (Commissioner).

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, as well as a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16877 Filed 8–6–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3369]

Evaluating the Clinical Pharmacology of Oligonucleotide Therapeutics; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on evaluating the clinical pharmacology of oligonucleotide therapeutics. There are many unique clinical pharmacology considerations concerning the development of oligonucleotide therapeutics; however, for the purposes of this request, the Agency is specifically interested in

comments regarding the characterization of the effects of hepatic and renal impairment, drug-drug interactions, and immunogenicity on the pharmacokinetics of oligonucleotide therapeutics as well as the effects of oligonucleotide therapeutics on cardiac electrophysiology. Public comments will help the Agency develop recommendations for the design and conduct of studies important to the safe and effective use of oligonucleotide therapeutics and facilitate the regulatory assessment of such studies.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment in our development of recommendations, submit either electronic or written information and comments by October 7, 2019.

ADDRESSES: You may submit comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3369 for ''Evaluating the Clinical Pharmacology of Oligonucleotide Therapeutics; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Hobart Rogers, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2213, *Hobart.Rogers@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Oligonucleotide therapeutics typically are synthetically modified single- or double-stranded ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) that exert pharmacologic effects through a variety of mechanisms (*e.g.,* altered splicing, RNA interference, immunomodulation, microRNA modulation). Compared to small molecule or biological products, oligonucleotide therapeutics have unique characteristics regarding their chemistry, pharmacology, sites of action, pharmacokinetic disposition, and pharmacodynamics. As a result, there may be special considerations for the design and conduct of clinical pharmacology studies to assess oligonucleotide therapeutics, such as those designed to evaluate the effects of organ impairment or drug interactions. Currently, none of FDA's currently published guidance documents on clinical pharmacology assessments contain specific recommendations for oligonucleotide therapeutics.

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on certain aspects of evaluating the clinical pharmacology of oligonucleotide therapeutics. This request focuses on oligonucleotide therapeutics designed to hybridize to a cognate RNA to elicit a pharmacologic effect. For all questions, organize any discussion by the type of oligonucleotide therapeutics (*e.g.,* by chemistry or modification type). Please provide the rationale for your suggestions and include supporting data if available. FDA is particularly interested in responses to the following overarching questions:

(1) Evaluating Drug-Drug Interactions (DDIs)

(a) Under what circumstances should clinical DDI assessment be warranted or not warranted for oligonucleotide therapeutics?

(b) In circumstances where DDI assessments are warranted:

(i) What types of DDI assessments are suitable and why (*e.g.,* in vitro studies, dedicated clinical studies, cocktail 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.,* in vitro test

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]

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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/.*