Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of DFI without concomitant bone and joint involvement. Specifically, this guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for the development of drugs to support an indication for treatment of DFI.

This guidance finalizes the draft guidance entitled ''Diabetic Foot Infections: Developing Drugs for Treatment'' issued on October 17, 2023 (88 FR 71578). FDA reviewed public comments on the published draft guidance and determined, after careful consideration, that no revisions were needed to finalize the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Diabetic Foot Infections: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 pertaining to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 201.56 and 201.57 relating to prescription product labeling requirements have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13237 Filed 6–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0235]

Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics; Guidance for Industry; 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 a final guidance for industry entitled ''Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics,'' which provides recommendations for the development of oligonucleotide therapeutics. Specifically, this guidance addresses FDA's current thinking regarding clinical pharmacology considerations and recommendations for oligonucleotide therapeutic development programs, including characterizing the potential for QT interval prolongation, performing immunogenicity risk assessment, characterizing the impact of hepatic and renal impairment, and assessing the potential for drug-drug interactions. This guidance finalizes the draft guidance of the same name issued on June 27, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on June 17, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2022–D–0235 for ''Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Anuradha Ramamoorthy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–6426, *Anuradha.Ramamoorthy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics.'' Oligonucleotide therapeutics are an emerging therapeutic modality with increasing numbers of drugs in development. While antisense and siRNA oligonucleotide therapeutics have been approved in recent years to treat rare diseases, many oligonucleotide therapeutics are in development to treat common chronic diseases. This guidance provides recommendations to assist industry in the development of oligonucleotide therapeutics. Specifically, this guidance represents FDA's recommendations for certain pharmacokinetic and pharmacodynamic investigations including characterizing QT interval prolongation potential, performing immunogenicity risk assessment, characterizing the impact of hepatic and renal impairment, and assessing the potential for drug-drug interactions during oligonucleotide therapeutic development. This guidance provides recommendations on when these assessments may be appropriate and what types of assessments can help address these issues.

This guidance finalizes the draft guidance of the same name issued on June 27, 2022 (87 FR 38161). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) updates to terms used in the guidance to provide clarity, (2) additional references to FDA guidance that have been published since publication of the draft guidance, and (3) editorial changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13271 Filed 6–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Nephrology and Urology.

Date: July 10, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Stacey Nicole Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *stacey.williams@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Respiratory Sciences Activities.

Date: July 10–11, 2024.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 (In-Person Meeting).

Contact Person: Imoh S. Okon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–347–8881, *imoh.okon@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Diseases and Immunology B Review Panel.

Date: July 10–11, 2024.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: North Bethesda Marriott Hotel & Conference Center, Montgomery County