

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]

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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

Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852 (In-Person Meeting).

Contact Person: Diana Maria Ortiz-Garcia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-5614, diana.ortiz-garcia@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Instrumentation, Environmental, and Occupational Safety.

Date: July 10-11, 2024.

Time: 8:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: North Bethesda Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852 (In-Person Meeting).

Contact Person: Joonil Seog, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-9791, joonil.seog@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Musculoskeletal, Skin and Oral Sciences.

Date: July 10-11, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 (In-Person Meeting).

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, (301) 496-8551, ingrahamrh@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Transformative Research to Address Health Disparities and Advance Health Equity.

Date: July 10-11, 2024.

Time: 9:00 a.m. to 7:00 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: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443-7193, hargravesl@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Muscle and Exercise Physiology/Musculoskeletal Rehabilitation Sciences Study Sections.

Date: July 10, 2024.

Time: 9:30 a.m. to 6:00 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: Yanming Bi, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 451-0996, ybi@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Innovation Research/Small Business Technology Transfer: Clinical Care and Health Interventions.

Date: July 10-11, 2024.

Time: 9:30 a.m. to 7:00 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: Joann Wu Shortt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-3333, shorttjw@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Basic Cancer Immunobiology.

Date: July 10-11, 2024.

Time: 10:00 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: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301-402-4788, sarita.sastry@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Anti-Infective Therapeutics.

Date: July 10-11, 2024.

Time: 10:00 a.m. to 10:00 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: Marcus Ferrone, PHARMD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-2371, marcus.ferrone@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; HAMI Hypersensitivity and Mucosal Immunology.

Date: July 10-11, 2024.

Time: 10:00 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: Deanna C. Bublitz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-4005, deanna.bublitz@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 11, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2008-0010]

Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The Board of Visitors for the National Fire Academy (Board) will meet in person at the National Emergency Training Center in Emmitsburg, MD, and virtually on Monday, August 5, 2024. The meeting will be open to the public.

DATES: The meeting will take place on Monday, August 5, 2024, 8 a.m. to 4 p.m. eastern time. Please note that the meeting may close early if the Board has completed its business.

ADDRESSES: Members of the public who wish to participate in the virtual conference should contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section by close of business on August 1, 2024, to obtain the call-in number and access code for the August 5th in-person and virtual meeting. For more information on services for individuals with disabilities or to request special assistance, contact Deborah Gartrell-Kemp as soon as possible. The Board is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Participants seeking to have their comments considered during the meeting should submit them in advance or during the public comment segment. Comments submitted up to 30 days after the meeting will be included in the public