

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the Docket No. FDA-2017-D-5297 for “Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations; Draft Guidance for Industry; Availability.” 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Adebayo Laniyonu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5400, Silver Spring, MD 20993-0002, 301-796-1392.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations.” This draft guidance is intended to assist developers of microdose radiopharmaceutical diagnostic drugs on the nonclinical studies recommended to support human clinical trials and marketing authorization. The draft guidance discusses how to refine nonclinical study recommendations for this class of drug given its unique characteristics. This draft guidance is intended to provide recommendations for a pathway to full drug development (marketing authorization) for microdose radiopharmaceutical diagnostic drugs.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on nonclinical studies recommended for microdose radiopharmaceutical

diagnostic drugs. 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively. The collection of information for radioactive drug research committees in 21 CFR 361.1 has been approved under OMB control number 0910-0053. The collection of information for the regulations on in vivo radiopharmaceuticals used for diagnosis and monitoring in 21 CFR 315.4, 315.5, and 315.6 has been approved under OMB control number 0910-0409.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-19435 Filed 9-12-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Government owned intellectual property covering HIV-1 reverse transcriptase inhibitors available for licensing and commercialization.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of

Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology available for licensing follows.

Pyrophosphate Analog HIV-1 Reverse Transcriptase Inhibitors

Description of Technology: The invention relates to compounds that inhibit HIV-1 DNA synthesis mediated by reverse transcriptase (RT). HIV-1 DNA synthesis by RT utilizes deoxynucleoside 5'-triphosphate (dNTP) as substrate and like many other enzymes, the reaction is reversible. Pyrophosphate analogs like imidodiphosphate strongly promote reverse reaction dNTP products containing the imidodiphosphate group instead of the naturally occurring pyrophosphate group. This imidodiphosphate-containing dNTP was found to be a potent inhibitor of the forward RT reaction. Whereas pyrophosphorolysis is limited by a nonchemical step, replacing the bridging oxygen of pyrophosphate with an imido group resulted in a change in the rate-limiting step, so that the imidodiphosphate-dependent reverse reaction was limited by chemistry. There exists, then, the potential to use pyrophosphate analogs therapeutically.

Potential Commercial Applications:

- Anti-microbial.
- HIV therapeutic.

Development Stage:

- In vitro data available.

Inventors: Samuel Wilson, William Beard, David Dion Shock (all of NIEHS).

Intellectual Property: HHS Reference No. E-210-2017/0-US-01.

- U.S. Provisional Patent Application 62/542,600 filed August 8, 2017.

Licensing Contact: Michael Shmilovich, Esq. CLP; 301-435-5019; shmilovm@nih.gov.

Collaborative Research Opportunity: The National Institute of Environmental Health Sciences seeks statements of capability or interest from parties interested in collaborative research to

further develop and evaluate, please contact Sally E. Tilotta, Ph.D., Director, Office of Technology Transfer, National Institute of Environmental Health Sciences, Phone: (919) 316-4526; sally.tilotta@nih.gov.

Dated: September 7, 2017.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2017-19315 Filed 9-12-17; 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 10(d) 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 Shared Instruments: NMR spectrometers and X-ray crystallography/scattering.

Date: October 3, 2017.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: David R Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435-1722, jollieda@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Shared Instruments: NMR spectrometers and X-ray crystallography/scattering.

Date: October 3, 2017.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: James W Mack, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435-2037, mackj2@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group Community Influences on Health Behavior Study Section.

Date: October 4-5, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Tasmeen Weik, DRPH, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, 301-827-6480, weikts@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Lymphatics in Health and Disease in the Digestive System, Kidney and Urinary Tract.

Date: October 4, 2017.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301-827-4417, jianxinh@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group Neurogenesis and Cell Fate Study Section.

Date: October 5, 2017.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435-1178, fujij@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group Developmental Therapeutics Study Section.

Date: October 5-6, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Sharon K Gubanich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 408-9512, gubanics@csr.nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 5-6, 2017.