

that it agreed to withdrawal of the application for this reason only.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 214622 for TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: May 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-10714 Filed 5-15-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; XOLREMDI (mavorixafor)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that XOLREMDI (mavorixafor), approved on April 26, 2024, manufactured by X4 Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to

sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that XOLREMDI (mavorixafor), manufactured by X4 Pharmaceuticals, Inc., meets the criteria for a priority review voucher. XOLREMDI (mavorixafor) is indicated for the treatment of WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome in patients 12 years of age and older to increase the number of circulating mature neutrophils and lymphocytes.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about XOLREMDI (mavorixafor), go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: May 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-10715 Filed 5-15-24; 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: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: June 6-7, 2024.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435-1712, ryansj@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: June 10-11, 2024.

Time: 9:00 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: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, (301) 435-6809, beheraak@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: June 11-12, 2024.

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

Agenda: To review and evaluate grant applications.

Place: The Bethesda Hotel, 8120 Wisconsin Avenue, Bethesda, MD 20814 (In Person).

Contact Person: Zachary Stephen Bailey, Ph.D., Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-4691, zach.bailey@nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Pain and Itch Study Section.

Date: June 11-12, 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 (In Person and Virtual Meeting).

Contact Person: Anne-Sophie Marie Lucie Wattiez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-4642, anne-sophie.wattiez@nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis, Thrombosis, Blood Cells and Transfusion Study Section.

Date: June 11-12, 2024.

Time: 8:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Bethesda Hotel, 8120 Wisconsin Avenue, Bethesda, MD 20814 (In Person).

Contact Person: Vivian Tang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-6208, tangvw@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: June 11–12, 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: Alexei A Yeliseev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443–0552, yeliseeva@mail.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: June 11–12, 2024.

Time: 9:30 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: Christine Jean DiDonato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1014J, Bethesda, MD 20892, (301) 435–1042, didonatocj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Academic-Industrial Partnerships for Translation of Technologies.

Date: June 11–12, 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: Jennifer Ann Sanders, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–3553, jennifer.sanders@nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: June 11–12, 2024.

Time: 10:00 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: Victoria Martinez Virador, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–4703, victoria.virador@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: May 10, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10716 Filed 5–15–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel, NICHD Bio-Specimen Repository, June 18, 2024, 10 a.m. to June 18, 2024, 4 p.m., Eunice Kennedy Shriver National Institute of Child, 6710B Rockledge Drive, Bethesda, MD, 20892, which was published in the **Federal Register** on May 07, 2024, FR Doc. No. 2024–09946, 89 FR 38167.

This notice is being amended to change the date of the meeting from June 18, 2024, to June 25, 2024. The time of the meeting will remain the same: 10 a.m. to 4 p.m. The meeting is closed to the public.

Dated: May 10, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10712 Filed 5–15–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

The meeting 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Research Tools for Difficult to Culture Eukaryotic Pathogens (R61/R33 Clinical Trial Not Allowed).

Date: June 11–12, 2024.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Richard G. Kostriken, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, 240–669–2075, richard.kostriken@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 13, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10724 Filed 5–15–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2024–0002]

Changes in Flood Hazard Determinations

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

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.