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for TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d).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 Bethesdan 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 Bethesdan 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*.