• SEKISUI Diagnostics, LLC's OSOM Flu SARS–CoV–2 Combo Test, issued on February 29, 2024.[5]

• CorDx, Inc.'s, CorDx Tyfast Flu A/B & COVID–19 Multiplex Rapid Test, issued on March 21, 2024;[6]

• OSANG LLC's OHC COVID–19/Flu Antigen Test Pro, issued on March 21, 2024.[7]

• OSANG LLC's QuickFinder COVID–19/Flu Antigen Self Test, issued on April 3, 2024.[8]

• CorDx, Inc.'s CorDx TyFast Flu A/B & COVID–19 At Home Multiplex Rapid Test, issued on April 5, 2024;[9] and

• Wondfo USA Co., Ltd.'s WELLlife COVID–19/Influenza A&B Test, issued on April 19, 2024.[10]

Dated: May 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10717 Filed 5–15–24; 8:45 am]

BILLING CODE 4164–01–P

[5] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[7] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[8] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[9] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[10] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2178]

Helsinn Healthcare SA; Withdrawal of Approval of New Drug Application for TRUSELTIQ (Infigratinib Phosphate) Capsules, 25 Milligrams and 100 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for TRUSELTIQ (infigratinib phosphate) Capsules, 25 milligrams (mg) and 100 mg, held by Helsinn Healthcare SA, C/O Helsinn Therapeutics (U.S.), Inc. (Helsinn), 200 Wood Ave. South, Suite 100, Iselin, NJ 08830. Helsinn has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of May 16, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 28, 2021, FDA approved NDA 214622 for TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (advanced bile duct cancer or advanced cholangiocarcinoma) with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, for advanced bile duct cancer or advanced cholangiocarcinoma included required postmarketing trials intended to verify the clinical benefit of TRUSELTIQ.

On October 5, 2022, Helsinn voluntarily requested withdrawal of approval of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg. On February 15, 2023, FDA recommended that the applicant submit a letter to voluntarily request withdrawal of approval of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, according to § 314.150(d) (21 CFR 314.150(d)) due to the company's inability to conduct a clinical trial to verify clinical benefit. On April 21, 2023, FDA requested Helsinn waive its opportunity for a hearing.

On May 30, 2023, Helsinn submitted a letter asking FDA to withdraw approval of NDA 214622 for TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, according to § 314.150(d) and waiving its opportunity for a hearing. In its letter requesting withdrawal of approval, Helsinn stated that it is voluntarily requesting withdrawal due to difficulties in recruiting and enrolling study subjects for the required confirmatory clinical trial in first line cholangiocarcinoma (a new indication under investigation for TRUSELTIQ), and the determination that, as a result, continued distribution of TRUSELTIQ in second line cholangiocarcinoma (the accelerated approval indication) is not commercially reasonable. Helsinn stated

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*.