

email at least 2 days prior to the meeting with information on how to access the virtual platform that will host the virtual breakout scenario discussions. Please note due to limited technology capacity, participation in the virtual breakout scenario discussions will be limited to 150 participants. Once capacity reaches 150 participants, the breakout session will be closed to additional participants. Additional information regarding the virtual breakout scenario discussions will be provided at <https://www.fdalive.com/peac>.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, or 240-507-6496 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-19323 Filed 8-27-24; 8:45 am]

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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; LIVMARLI (maralixibat)

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 LIVMARLI (maralixibat), approved on September 29, 2021, manufactured by Mirum 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, Cathryn.Lee@fda.hhs.gov.

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 LIVMARLI (maralixibat), manufactured by Mirum Pharmaceuticals, Inc., meets the criteria for a priority review voucher. LIVMARLI (maralixibat) oral solution is indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

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/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about LIVMARLI (maralixibat), go to the "Drugs@FDA" website at <https://>

www.accessdata.fda.gov/scripts/cder/daf/.

Dated: August 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-19334 Filed 8-27-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-P-0805]

Determination That FENTANYL CITRATE Injections, Equivalent to 2.5 Milligram Base/50 Milliliter and Equivalent to 5 Milligram Base/100 Milliliter, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that FENTANYL CITRATE Injections, equivalent to 2.5 milligram (mg) base/50 milliliter (mL) (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Swati Rawani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993-0002, 240-402-9917, Swati.Rawani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved; and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain

approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), are the subject of NDA 215870, held by Exela Pharma Sciences, LLC, and initially approved on February 8, 2023. FENTANYL CITRATE is indicated in adult and pediatric patients ages 2 years and older for use as an opioid analgesic supplement in general anesthesia, for administration with a neuroleptic for the induction of anesthesia and as an adjunct in the maintenance of general anesthesia, and for use as an anesthetic agent with oxygen in selected high-risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

Exela Pharma Sciences, LLC, has never marketed FENTANYL Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL). In a letter dated May 5, 2023, Exela Pharma Sciences, LLC, notified FDA that FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), were being discontinued, and FDA moved these drug products to the “Discontinued Drug Product List” section of the Orange Book. In previous instances (see, e.g., 72 FR 9763 (March 5, 2007) and 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated February 13, 2024 (Docket No. FDA–2024–P–0805), under 21 CFR 10.30, requesting that the Agency determine whether FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), from sale. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to FENTANYL CITRATE Injections, EQ 2.5 mg base/50 mL (EQ 0.05 mg base/mL) and EQ 5 mg base/100 mL (EQ 0.05 mg base/mL), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19333 Filed 8–27–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel: NIEHS Support for Conferences and Scientific Meeting R13.

Date: September 27, 2024.

Time: 11:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Murali Ganesan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training (DERT), National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, Room 3097, Research Triangle Park, NC 27713, Phone: 984–287–4674, Email: murali.ganesan@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 23, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–19319 Filed 8–27–24; 8:45 am]

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