

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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

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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.

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