

effectiveness. The petitioner has identified no data or other information suggesting that QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/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 QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-11802 Filed 6-4-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-P-2174]

Determination That ATROVENT (Ipratropium Bromide) Metered Spray, 0.021 Micrograms/Spray and 0.042 Micrograms/Spray, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that ATROVENT (ipratropium bromide) metered spray, 0.021 micrograms (mcg)/spray and 0.042 mcg/spray, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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.

ATROVENT (ipratropium bromide) metered spray, 0.021 mcg/spray, is the subject of NDA 020393 and ATROVENT (ipratropium bromide) metered spray, 0.042 mcg/spray, is the subject of NDA 020394, both held by Boehringer Ingelheim Pharmaceuticals, Inc., and initially approved on October 20, 1995. ATROVENT is indicated for the symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in adults and children age 6 years and older.

In letters dated December 22, 2017, Boehringer Ingelheim Pharmaceuticals, Inc., requested withdrawal of NDA 020393 and NDA 020394 for ATROVENT (ipratropium bromide). In the **Federal Register** of July 12, 2018 (83 FR 32305), FDA announced that it was withdrawing approval of NDA 020393 and NDA 020394, effective August 13, 2018.

Lachman Consulting Services, Inc., submitted a citizen petition dated November 5, 2020 (Docket No. FDA-2020-P-2174), under 21 CFR 10.30, requesting that the Agency determine whether ATROVENT (ipratropium bromide) metered spray, 0.021 mcg/spray and 0.042 mcg/spray, 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 ATROVENT (ipratropium bromide) metered spray, 0.021 mcg/spray and 0.042 mcg/spray, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ATROVENT (ipratropium bromide) metered spray, 0.021 mcg/spray and 0.042 mcg/spray, were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ATROVENT (ipratropium bromide) metered spray, 0.021 mcg/spray and 0.042 mcg/spray, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ATROVENT (ipratropium bromide) metered spray, 0.021 mcg/spray and 0.042 mcg/spray, 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.

FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for this drug product may also 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: May 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-11800 Filed 6-4-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) 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 on Aging Special Emphasis Panel; Multi-Component Application.

Date: July 21, 2021.

Time: 12:45 p.m. to 5:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Dario Dieguez, Jr., Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301.827.3101, dario.dieguez@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: June 2, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-11880 Filed 6-4-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK F99/K99 Special Emphasis Panel.

Date: June 23, 2021.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Peter J. Kozel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7119, Bethesda, MD 20892-5452, 301-594-7271, kozellp@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 2, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-11881 Filed 6-4-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) 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: National Cancer Institute Special Emphasis Panel; PLCO Biospecimens Resource U01 SEP.

Date: July 1, 2021.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Branch Chief, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, Maryland 20850, 240-276-6442, ahmads@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Collaborative Research at the NIH Clinical Center (U01).

Date: July 1, 2021.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W240, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Hasan Siddiqui, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609, Medical Center Drive, Room 7W240, Rockville, Maryland 20850, 240-276-5122, hasan.siddiqui@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)