ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
	Vaccination of critical workforce (functional exercise, full-scale exercise, or incident).	62	1	12/60
	Vaccination of critical workforce (point of dispensing/dispensing/vaccination clinic setup).	62	1	12/60
	Vaccination of critical workforce (immunization information system).	62	1	12/60
	Five-year distribution FSE OR five-year pandemic influenza full-scale exercise.	62	1	0.5
PHEP Awardees: Major Metropolitan Area Jurisdictions.	Facility setup drill	4	1	45/60
	Site activation drill	4	1	1
	Staff notification and assembly drill	4	1	1
	Dispensing throughput drill	4	1	12/60
	Five-year dispensing full-scale exercise or incident.	4	1	6/60
	Five-year dispensing full-scale exercise for each point of dispensing site exercised.	4	1	6/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–11872 Filed 6–4–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–2317]

Determination That QUELICIN PRESERVATIVE FREE (Succinylcholine Chloride) Injection, 20 Milligrams/Milliliter, 50 Milligrams/Milliliter, and 100 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 milligrams (mg)/milliliter (mL), 50 mg/mL, and 100 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3601, *Nicole.Mueller@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.

QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, is the subject of NDA 008845, held by Hospira, Inc., and initially approved on May 1, 1953. QUELICIN PRESERVATIVE FREE is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Baxter Healthcare Corp. submitted a citizen petition dated December 21, 2020 (Docket No. FDA–2020–P–2317), under 21 CFR 10.30, requesting that the Agency determine whether QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, was 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 QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/mL, 50 mg/mL, and 100 mg/mL, was not withdrawn for reasons of safety or

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]

BILLING CODE 4164–01–P

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 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 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''