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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22676 Filed 12–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–1617]

Determination That BACTROBAN (Mupirocin) Nasal Ointment, 2%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that BACTROBAN (mupirocin) nasal ointment, 2%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for mupirocin nasal ointment, 2%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Iris Masucci, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–3600, *iris.masucci@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C 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, a drug is 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

BACTROBAN (mupirocin) nasal ointment, 2%, is the subject of NDA 050703, held by SmithKline Beecham (Cork) Ltd., Ireland/GlaxoSmithKline (GSK), and was initially approved on September 18, 1995. BACTROBAN nasal ointment, 2%, is indicated for the eradication of nasal colonization with methicillin-resistant *Staphylococcus aureus* (MRSA) in adult and pediatric patients (aged 12 years and older) and healthcare workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of MRSA infection during institutional outbreaks of infections with this microorganism.

In a correspondence dated February 9, 2018, GSK notified FDA that BACTROBAN (mupirocin) nasal ointment, 2%, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated January 5, 2022, GSK requested withdrawal of NDA 050703 for BACTROBAN (mupirocin) nasal ointment, 2%, under § 314.150(c) (21 CFR 314.150(c)). In the **Federal Register** of August 4, 2025, FDA announced that it was withdrawing approval of NDA 050703 upon request of GSK under § 314.150(c), effective September 3, 2025.

E4 Consulting submitted a citizen petition dated June 24, 2020 (Docket No. FDA–2020–P–1617), under 21 CFR 10.30, requesting that the Agency determine whether BACTROBAN (mupirocin) nasal ointment, 2%, 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 BACTROBAN (mupirocin) nasal ointment, 2%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BACTROBAN (mupirocin) nasal ointment, 2%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BACTROBAN (mupirocin) nasal ointment, 2%, 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 this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BACTROBAN (mupirocin) nasal ointment, 2%, 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 BACTROBAN (mupirocin) nasal ointment, 2%, 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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22682 Filed 12–11–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2952]

Determination That LUNELLE (Estradiol Cypionate and Medroxyprogesterone Acetate) Injectable, 5 Milligrams/0.5 Milliliter and 25 Milligrams/0.5 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 LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 milligrams (mg)/0.5 milliliter (mL) estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for estradiol cypionate and medroxyprogesterone acetate injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Grace St.Vincent, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6215, Silver Spring, MD 20993–0002, 240–402–9201, *Grace.StVincent@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C 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.

LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, is the subject of NDA 020874, held by Pharmacia and Upjohn Co., and initially approved on October 5, 2000. LUNELLE is indicated for the prevention of pregnancy.

In a letter dated June 24, 2003, Pharmacia and Upjohn Co. requested withdrawal of NDA 020874 for LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of NDA 020874, effective June 4, 2004.

Sarah A. Norring, Ph.D. submitted a citizen petition dated June 20, 2024 (Docket No. FDA–2024–P–2952), under 21 CFR 10.30, requesting that the Agency determine whether LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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 LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, was not withdrawn for reasons of safety or effectiveness. The petitioner provided information about a voluntary recall of prefilled syringes of LUNELLE in October 2002 due to potential manufacturing issues at a particular facility. We have carefully reviewed our files for records concerning the withdrawal of LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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 LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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 LUNELLE (estradiol cypionate and medroxyprogesterone acetate) injectable, 5 mg/0.5 mL estradiol cypionate and 25 mg/0.5 mL medroxyprogesterone acetate, 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.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22680 Filed 12–11–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4734]

Determination That DEMEROL (Meperidine Hydrochloride) Tablet, 100 Milligrams, and Other Drug Products 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 the drug products listed in this document 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.*