their roles, and to prevent browsing. The records are processed and stored in a secure environment. All records are stored in an area that is always physically safe from unauthorized access. Safeguards conform to the HHS Information Security and Privacy Program, which may be found at *https://www.hhs.gov/ocio/securityprivacy/index.html.*

RECORD ACCESS PROCEDURES:

To request access to a record about you in this system of records, submit a written access request to the System Manager. The request must include your name, telephone number or email address, current address, signature, and sufficient particulars (such as date of birth or SSN) to enable the System Manager to distinguish between records on subject individuals with the same name. To verify your identity, your signature must be notarized, or your request must include your written certification that you are the individual who you claim to be and that you understand that the knowing and willful request for, or acquisition of, a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000.

CONTESTING RECORD PROCEDURES:

To request correction of a record about you in this system of records, submit a written amendment request to the System Manager. The request must contain the same information required for an access request and include verification of your identity in the same manner required for an access request. In addition, the request must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; it should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

To find out if this system of records contains a record about you, submit a written notification request to the System Manager. The request must identify this system of records, contain the same information required for an access request, and include verification of your identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

87 FR 3553 (Jan. 24, 2022).

[FR Doc. 2024–07668 Filed 4–10–24; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–5095]

Determination That VISTARIL (Hydroxyzine Pamoate) Oral Suspension, 25 Milligrams/5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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, Agency, or we) has determined that VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 milligrams (mg)/5 milliliters (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 VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@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.

VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, is the subject of NDA 011795, held by Pfizer Inc., and initially approved on June 3, 1959. VISTARIL is indicated for symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested. It is also useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus. It is also indicated as a sedative when used as premedication and following general anesthesia. VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated November 17, 2023 (Docket No. FDA–2023–P–5095), under 21 CFR 10.30, requesting that the Agency determine whether VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, has been voluntarily withdrawn 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 VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 mL, 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 VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 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 VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 mg/5 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: April 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07707 Filed 4–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–4587]

Determination That KEMSTRO (Baclofen) Orally Disintegrating Tablets, 10 Milligrams and 20 Milligrams, 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, Agency, or we) has determined that KEMSTRO (baclofen) orally disintegrating tablets, 10 milligrams (mg) and 20 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for baclofen orally disintegrating tablets, 10 mg and 20 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexander Poonai, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–9120, *Alexander.Poonai@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.

KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, are the subject of NDA 021589, held by UCB, Inc., and initially approved on October 30, 2003. KEMSTRO is indicated for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Pharmobedient Consulting, LLC, submitted a citizen petition dated October 16, 2023 (Docket No. FDA–2023–P–4587), under 21 CFR 10.30, requesting that the Agency determine whether KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, 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 KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, 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 KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, 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 KEMSTRO (baclofen) orally disintegrating tablets, 10 mg and 20 mg, may be approved by the Agency so 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: April 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07722 Filed 4–10–24; 8:45 am]

BILLING CODE 4164–01–P