



## 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### Determination That VISTARIL (Hydroxyzine Pamoate) Oral Suspension, 25 Milligrams/5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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we) has determined that VISTARIL (hydroxyzine pamoate) Oral Suspension, 25 milligrams (mg)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.*

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