



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2025-P-1028]**

### **Determination That SEMPREX-D (Acrivastine and Pseudoephedrine Hydrochloride) Capsules, 8 Milligrams and 60 Milligrams, Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness**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that SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 milligrams (mg) and 60 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for acrivastine and pseudoephedrine hydrochloride capsules, 8 mg and 60 mg, if all other legal and regulatory requirements are met.

**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](mailto:Stacy.Kane@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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 mg, is the subject of NDA 019806, held by Endo Pharmaceuticals, and initially approved on March 25, 1994. SEMPREX-D is indicated for relief of symptoms associated with seasonal allergic rhinitis such as sneezing, rhinorrhea, pruritus, lacrimation, and nasal congestion.

In a letter dated August 3, 2020, Endo Pharmaceuticals notified FDA that SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 mg, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Pharmobedient Consulting, LLC submitted a citizen petition dated April 1, 2025 (Docket No. FDA-2025-P-1028), under 21 CFR 10.30, requesting that the Agency determine whether SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 mg, 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 SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 mg, was not withdrawn

for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 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 this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 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 SEMPREX-D (acrivastine and pseudoephedrine hydrochloride) capsules, 8 mg and 60 mg, 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.

**Grace R. Graham,**

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

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