

**Brian Fahey,**

*Associate Commissioner for Legislation.*

[FR Doc. 2025–23483 Filed 12–18–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–N–4683]

#### Issuance of Priority Review Voucher; Rare Pediatric Disease Product; FORZINITY (Elamipretide)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that FORZINITY (elamipretide), approved September 19, 2025, manufactured by Stealth BioTherapeutics Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:**

Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993–0002, 301–796–2771, [Quyen.Tran1@fda.hhs.gov](mailto:Quyen.Tran1@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined FORZINITY (elamipretide) manufactured by Stealth BioTherapeutics Inc., meets the criteria for a priority review voucher. FORZINITY (elamipretide) injection is indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriority>

*VoucherProgram/default.htm*. For further information about FORZINITY (elamipretide), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

**Lowell M. Zeta,**

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

[FR Doc. 2025–23409 Filed 12–18–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–P–1562]

#### Determination That DEXCHLORPHENIRAMINE MALEATE (Dexchlorpheniramine Maleate, Oral Syrup, 2 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 DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 milligrams (mg)/5 milliliters (ml)), was 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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:**

Molly Arndt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6281, Silver Spring, MD 20993–0002, 240–402–6919, [Molly.Arndt@fda.hhs.gov](mailto:Molly.Arndt@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.

DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 mg/5 ml), is the subject of ANDA 088251, held by PAI Holdings, LLC, and initially approved on March 23, 1984. DEXCHLORPHENIRAMINE MALEATE is indicated for

- Perennial and seasonal allergic rhinitis
- Vasomotor rhinitis
- Allergic conjunctivitis due to inhaled allergens and foods
- Mild, uncomplicated allergic skin manifestations of urticaria and angioedema
- Amelioration of allergic reactions to blood or plasma
- Dermographism
- As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled

On March 8, 2024, PAI Holdings, LLC, notified FDA that DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 mg/5 ml), 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 June 4, 2025 (Docket No. FDA–2025–P–1562), under 21 CFR 10.30, requesting that the Agency determine whether DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral