

ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, is the subject of NDA 020699, held by Upjohn US, and initially approved on October 20, 1997. EFFEXOR XR is indicated in adults for the treatment of major depressive disorder, generalized anxiety disorder, social anxiety disorder and panic disorder. EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

SciRegs International, Inc., on behalf of Inventia Healthcare Limited, submitted a citizen petition dated May 16, 2025 (Docket No. FDA-2025-P-1304) under 21 CFR 10.30, requesting that the Agency determine whether EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, was withdrawn from sale for reasons of safety or effectiveness.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 EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, was not

withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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 EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-N-5603; FDA-2024-N-4731; FDA-2024-N-5468; FDA-2024-N-5234; FDA-2025-N-0123; FDA-2025-N-0383; FDA-2025-N-0338; FDA-2025-N-0183; FDA-2025-N-0349; FDA-2025-N-0082]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
New Animal Drug and Veterinary Master Files	0910-0032	9/30/2028
Administrative Detention and Banned Medical Devices	0910-0114	9/30/2028
Food and Drug Administration’s Adverse Event and Product Experience Reporting Program	0910-0291	9/30/2027
Notification Procedures for Statements of Dietary Supplements	0910-0331	9/30/2028
Substances Generally Recognized as Safe (GRAS): Notifications and Convening Panels	0910-0342	9/30/2028
Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation	0910-0456	9/30/2028
Export Notification and Recordkeeping Requirements	0910-0482	9/30/2028
Establishing and Maintaining Lists of United States Establishments With Interest in Exporting Human Food Program-Regulated Products	0910-0509	9/30/2028
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	0910-0752	9/30/2028
Compounding Animal Drugs From Bulk Drug Substances	0910-0904	9/30/2028

Brian Fahey,

Associate Commissioner for Legislation.

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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.

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.

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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.

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