DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3466]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; MRESVIA (Respiratory Syncytial Virus Vaccine)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. 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 issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that MRESVIA (Respiratory Syncytial Virus Vaccine), BLA supplement approved June 12, 2025, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, *industry.biologics@fda.hhs.gov,* 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that MRESVIA (Respiratory Syncytial Virus Vaccine) meets the redemption criteria.

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/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about MRESVIA (Respiratory Syncytial Virus Vaccine), go to the Center for Biologics Evaluation and Research Approved Products website at: *https://www.fda.gov/vaccines-blood-biologics/center-biologics-evaluation-and-research-cber-product-approval-information.*

Grace R. Graham,

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–4151]

Determination That REVIA (Naltrexone Hydrochloride) Tablets, 50 Milligrams Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 REVIA (naltrexone hydrochloride) tablets, 50 milligrams (mg), 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.

REVIA (naltrexone hydrochloride) tablets, 50 mg, is the subject of NDA 018932, held by Teva Women's Health, Inc., and initially approved on November 20, 1984. REVIA is indicated for the treatment of alcohol dependence and for the blockade of the effects of exogenously administered opioids.

In a letter dated May 16, 2018, Teva Women's Health, Inc. requested withdrawal of NDA 018932 for REVIA (naltrexone hydrochloride) tablets, 50 mg. In the **Federal Register** of April 1, 2019 (84 FR 12262), FDA announced that it was withdrawing approval of NDA 018932, effective May 1, 2019.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated September 22, 2025 (Docket No. FDA–2025–P–4151), under 21 CFR 10.30, requesting that the Agency determine whether REVIA (naltrexone hydrochloride) tablets, 50 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 REVIA (naltrexone hydrochloride) tablets, 50 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REVIA (naltrexone hydrochloride) tablets, 50 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REVIA (naltrexone hydrochloride) tablets, 50 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have