

reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REVIA (naltrexone hydrochloride) tablets, 50 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.

**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-2026-N-3447]

#### Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; MNEXSPIKE (COVID-19 Vaccine, mRNA)

**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 MNEXSPIKE (COVID-19 Vaccine, mRNA), approved May 30, 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](mailto: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 MNEXSPIKE (COVID-19 Vaccine, mRNA) 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 MNEXSPIKE (COVID-19 Vaccine, mRNA), 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

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Transforming Pediatrics for Early Childhood Program Performance Measures

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than June 15, 2026.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Transforming Pediatrics for Early Childhood Program Performance Measures, OMB No. 0906-New.

*Abstract:* The Transforming Pediatrics for Early Childhood (TPEC) Program is authorized by 42 U.S.C. 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act), which authorizes awards for special projects of regional and national significance in maternal and child health. Special projects of regional and national significance support HRSA’s mission to improve the health and well-being of America’s mothers, children, and families. Through the TPEC Program, HRSA directly funds organizations with statewide or tribal reach to place early childhood development experts in local pediatric practices to deliver team-based care to young children and their families. All TPEC funding recipients will collect data and report standardized annual performance measures included in this ICR.

*Need and Proposed Use of the Information:* HRSA will use the information to monitor and provide oversight to TPEC funding recipients so the recipients can successfully access, analyze, and use pediatric practice-level and state-level data to meet program goals. HRSA will also use the performance information to demonstrate program accountability and impact to young children and their families served by the TPEC-funded pediatric practices.

*Likely Respondents:* TPEC funding recipients.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying