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: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

CARAFATE (sucralfate) oral suspension, 1 g/10 mL, is the subject of NDA 019183, held by Abbvie, Inc., and initially approved on December 16, 1993. CARAFATE is indicated in the short-term (up to 8 weeks) treatment of active duodenal ulcer.

CARAFATE (sucralfate) oral suspension, 1 g/10 mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Aurobindo Pharma USA, Inc., submitted a citizen petition dated July 6, 2026 (Docket No. FDA–2026–P–7537), under 21 CFR 10.30, requesting that the Agency determine whether CARAFATE (sucralfate) oral suspension, 1 g/10 mL, has been voluntarily 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 CARAFATE (sucralfate) oral suspension, 1 g/10 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CARAFATE (sucralfate) oral suspension, 1 g/10 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CARAFATE (sucralfate) oral suspension, 1 g/10 mL, 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 CARAFATE (sucralfate) oral suspension, 1 g/10 mL, 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.

[FR Doc. 2026–17968 Filed 9–1–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–9547]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; GENGLYCOS (parisglasgene brecaparvovec-opnr)

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 GENGLYCOS (parisglasgene brecaparvovec-opnr), approved on August 19, 2026, manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for 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 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 that GENGLYCOS (parisglasgene brecaparvovec-opnr), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher. GENGLYCOS (parisglasgene brecaparvovec-opnr) is an adeno-associated virus (AAV) vector-based gene therapy indicated to reduce daily cornstarch intake as an adjunct to nutritional management in adult and pediatric patients 8 years age and older with Glycogen Storage Disease Type la (GSDla).

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/industry/developing-products-rare-diseases-*

conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs. For further information about GENGLYCOS (parisglasgene brecaparvovec-opnr), go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17932 Filed 9–1–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; Matching Program

AGENCY: Department of Health and Human Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, and Office of Management and Budget (OMB) guidance on computer matching, the Department of Health and Human Services (HHS) is providing notice of the establishment of a new matching program. Pursuant to the Payment Integrity Information Act of 2019, HHS, including its component divisions and program offices, is establishing a new matching program consisting of the computerized comparison of an HHS system of records with the Do Not Pay (DNP) Working System, which is administered by Treasury's Bureau of the Fiscal Service. This matching program will enable HHS to compare records maintained in an HHS system of records covering HHS grantees and grant payments with records maintained in the DNP Working System for the purposes of identifying and preventing improper payments and conducting any related recovery activities.

DATES: Submit comments on or before October 2, 2026. This new matching program will be effective 30 days after publication of this notice through September 10, 2029.

ADDRESSES: Written comments on this notice may be submitted electronically through the Federal government eRulemaking portal at *http://www.regulations.gov;* docket number 2026–0364. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables HHS to make the comments available to the public. Please note that comments submitted through *https://www.regulations.gov* will be made available for viewing by the public.

Comments on this proposed matching program may also be addressed to U.S. Department of Health and Human Services, Attention: Hye J. (Sheri) Min, Director, Payment Management Services, 5600 Fishers Lane, Room 08N25, Rockville, MD 20852, or by email: *Hye.Min@psc.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Interested parties may submit written comments on this notice to the HHS Privacy Act Office by mail at: HHS Privacy Act Officer, 200 Independence Ave SW, Washington, DC 20201, or by email: *HHSPrivacyActOffice@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) amended the Privacy Act of 1974 (5 U.S.C. 552a) by establishing procedural safeguards related to agencies' use of records when performing certain types of computerized matching. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101– 508) further amended the Privacy Act regarding protections for individuals when agencies perform these functions.

Additionally, the Payment Integrity Information Act of 2019 (31 U.S.C. 3351 *et seq.*) provides the head of the agency operating the DNP Working System with the authority, in consultation with OMB, to waive the requirements in 5 U.S.C. 552a(o) in any case or class of cases for matching activities conducted under the DNP Initiative (31 U.S.C. 3354). Pursuant to this authority, the Secretary of the Treasury, after consulting with the OMB Director, authorized the issuance of a four-year waiver of the requirement for entering into a matching agreement under 5 U.S.C. 552a(o) for the class of matching programs that meet all of the criteria defined in OMB Memorandum M–25–32, *Preventing Improper Payments and Protecting Privacy through Do Not Pay.*

HHS has determined that the DNP matching program described in this notice is eligible for the waiver described in OMB Memorandum M–25–32, which is effective from September 10, 2025, through September 10, 2029.

For purposes of this notice, matches between HHS PMS and the DNP Working System constitute a single agency-wide matching program implementing DNP for all HHS grant payments.

Participating Agencies: HHS will match all HHS grantees it pays through the Payment Management System (PMS) with the DNP Working System, which is maintained by the Bureau of the Fiscal Service at the U.S. Department of the Treasury.

Authority for Conducting the Matching Program: The Payment Integrity Information Act of 2019 (31 U.S.C. 3351 *et seq.*) establishes the DNP Initiative and requires, for the purposes of identifying and preventing improper payments, each executive agency to have access to, and use of, the relevant databases in DNP to verify payment or award eligibility. Additional applicable authorities for this matching program include Executive Order 13520, *Reducing Improper Payments* (74 FR 62201); Executive Order 14249, *Protecting America's Bank Account Against Fraud, Waste, and Abuse* (90 FR 14011); and OMB Memorandum M–25–32, *Preventing Improper Payments and Protecting Privacy Through Do Not Pay.* Additional information regarding the statutory authorities for the collection and maintenance of information for HHS PMS is contained within the system of records notice listed below.

Purpose(s): The purpose of the matching program is to review payment eligibility to prevent, or identify and recoup, improper payments. Data elements that are necessary for payment eligibility determinations or recoupment for a relevant grant that are contained in records from an HHS system of records will be compared with records in the DNP Working System. When there is a match between a record provided by the HHS system and a record in the DNP Working System, the DNP Working System will notify the submitting HHS system of a potentially matching record and will identify the database(s) that contain(s) the potentially matching record(s). The grantor agency will then review the information to determine whether additional action is needed. If no matches are identified, the DNP Working System will provide a no-match response to the submitting HHS system.

Categories of Individuals: Recipients of HHS grant funds disbursed through HHS PMS.

Categories of Records: Information described in the Do Not Pay SORN will be used in concert with information described in HHS's Financial Management SORN to detect payees potentially ineligible for payment. Data will be matched across the two systems of records using identifiers that may include, as applicable, name (individual name and/or business/trading name); Taxpayer Identification Number (TIN, meaning Social Security Number (SSN), Employer Identification Number (EIN), or Individual Taxpayer Identification Number (ITIN)); Unique Entity Identifier