

must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Tong Zhou, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–0826, Tong.Zhou@fda.hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of final GFI #116 (VICH GL23(R2)) titled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2).” FDA has participated in efforts to enhance international harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use to develop harmonized technical requirements for the approval of human pharmaceutical and biological products

among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of founding member representatives from the European Commission and European Medicines Agency; AnimalhealthEurope; FDA—Center for Veterinary Medicine; the U.S. Department of Agriculture—Center for Veterinary Biologics; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry and Fisheries; and the Japanese Veterinary Products Association. There are 10 standing members to the VICH Steering Committee: one representative from government and one representative from industry of Australia, New Zealand, Canada, South Africa, and the United Kingdom. The World Organisation for Animal Health is an associate member of the VICH. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

This guidance document is intended to provide study design recommendations that will facilitate the mutual acceptance by the relevant regulatory authorities of safety data for the determination of Acceptable Daily Intakes (ADIs) for veterinary drug residues in human food. The guidance reflects the recommendations of the VICH set forth in the VICH GL23(R2) guideline.

In the **Federal Register** of September 30, 2024 (89 FR 79614), FDA published the notice of availability for a draft guidance titled “International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (Revision 2); Draft Guidance for Industry; Availability,” giving interested persons until November 29, 2024, to comment on the draft guidance. FDA received one comment on the draft guidance and this comment was considered as the guidance was finalized. After consideration of the comment received and revisions to the VICH guideline, a final draft of the guideline was submitted to the VICH Steering Committee and endorsed by the regulatory agencies in August 2025. The guidance announced in this notice

finalizes the draft guidance dated September 2024.

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

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–P–7537]

Determination That CARAFATE (Sucralfate) Oral Suspension, 1 Gram/10 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 CARAFATE (sucralfate) oral suspension, 1 gram (g)/10 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: 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.

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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 breccaparvovec-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 breccaparvovec-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 breccaparvovec-opnr), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher. GENGLYCOS (parisglasgene breccaparvovec-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 Ia (GSDIa).

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->