

Hallak, J.E.C., and R.G. Dos Santos, "Identifying setting factors associated with improved ibogaine safety: a systematic review of clinical studies," *Eur. Arch. Psychiatry Clin. Neurosci.*, 273(7):1527–1542 (2023), available at doi:10.1007/s00406-023-01590-1.

9. * U.S. Food and Drug Administration guidance for industry "E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers" (August 2022), available at <https://www.fda.gov/media/161198/download>.
10. * U.S. Food and Drug Administration guidance for industry "Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors" (August 2023), available at <https://www.fda.gov/media/88915/download>.
11. * U.S. Food and Drug Administration guidance for industry "E6(R3) Good Clinical Practice" (September 2025), available at <https://www.fda.gov/media/169090/download>.
12. * U.S. Food and Drug Administration guidance for industry "Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers" (July 2005), available at <https://www.fda.gov/media/72309/download>.
11. * U.S. Food and Drug Administration guidance for industry "QTc Information in Human Prescription Drug and Biological Product Labeling" (December 2025), available at <https://www.fda.gov/media/170814/download>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20427 Filed 10–5–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4291]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 15 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on May 7, 2026. The document announced the withdrawal of approval of 15 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of June 8, 2026. The document indicated that FDA was withdrawing approval of ANDA 210285 for dimethyl fumarate delayed-release

capsule, 120 milligrams (mg) and 240 mg, held by Upsher-Smith Laboratories, LLC., U.S. Agent for Sawai USA, Inc., 6701 Evenstad Dr. N, Suite 300, Maple Grove, MN 55369. Before FDA withdrew the approval of this ANDA, Upsher-Smith Laboratories, LLC., U.S. Agent for Sawai USA, Inc., informed FDA that they did not want the approval of the ANDA withdrawn. Because Upsher-Smith Laboratories, LLC., U.S. Agent for Sawai USA, Inc., timely requested that approval of the ANDA not be withdrawn, the approval is still in effect. This notice removes the entry for ANDA 210285.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, May 7, 2026 (91 FR 24879), appearing on page 24879 in FR Doc. 2026–09012, the following correction is made:

On page 24879, in the table, the entry for ANDA 210285 is removed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20460 Filed 10–5–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–11259]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; FAYUVI (rebisufligene etisparvovec-hopf)

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 FAYUVI (rebisufligene etisparvovec-hopf), approved on September 17, 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 FAYUVI (rebisufligene etisparvovec-hopf), manufactured by Ultragenyx Pharmaceutical Inc., meets the criteria for a priority review voucher. FAYUVI (rebisufligene etisparvovec-hopf) is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of neurologic manifestations of mucopolysaccharidosis type IIIA (MPS IIIA, Sanfilippo syndrome type A) in pediatric patients with preserved neurodevelopmental function.

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 FAYUVI (rebisufligene etisparvovec-hopf), 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. 2026–20434 Filed 10–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the President's Cancer Panel.