

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]

BILLING CODE 4164–01–P

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document announced the withdrawal of approval of 15 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of June 8, 2026.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]

BILLING CODE 4164–01–P

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.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed by clicking on the links below.

Name of Committee: President's Cancer Panel.

Date: October 15, 2026.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: Opportunities to Reduce Obesity-Related Cancer Risk: GLP-1 Medications.

Address: National Institutes of Health, 31 Center Drive, Room 11A30B, Bethesda, MD 20892.

Meeting Format: Virtual Meeting. Access to Meeting: <https://cbiit.webex.com/weblink/register/r8def1cffd7e6e17a9b599f8f3c6e9441>.

Contact Person: Samantha L. Finstad, Ph.D., Executive Secretary, President's Cancer Panel, Office of the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A30B, MSC 2590, Bethesda, MD 20892, 240-276-6460, samantha.finstad@nih.gov.

Registration is not required to attend this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the PCP website: <https://prescancerpanel.cancer.gov/>, where an agenda, instructions for accessing the virtual meeting, and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 1, 2026.

Kuleni D. Onnen,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-20424 Filed 10-5-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2026-0003; OMB No. 1660-0072]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; Hazard Mitigation Grant Programs

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. FEMA invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice seeks comments concerning the information collection instruments for Hazard Mitigation Grant Programs (HMA).

DATES: Comments must be submitted on or before November 5, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address FEMA-Information-Collections-Management@fema.dhs.gov or H-Camille Crain, Deputy Director, Documents, Design, Program Effectiveness Branch, FEMA, at 202-212-4871 or via email at H-Camille.Crain@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: This collection of information is necessary for eligibility determinations, grants management, and compliance with other Federal laws and regulations for HMA's financial and technical assistance programs. HMA programs

included in this information collection are the Flood Mitigation Assistance (FMA) program and FMA Swift Current (Swift Current), the Building Resilient Infrastructure and Communities (BRIC) program, BRIC Direct Technical Assistance (DTA), the Pre-Disaster Mitigation (PDM) program, the Safeguarding Tomorrow Revolving Loan Fund (RLF) Program, the Rehabilitation of High Hazard Potential Dams (HHPD), and the National Dam Safety Program (NDSP).

The FMA program and FMA's Swift Current is authorized by section 1366 of the National Flood Insurance Act of 1968, as amended (Pub. L. 90-448, 42 U.S.C. 4104c); the Flood Disaster Protection Act of 1973 (Pub. L. 93-234, 42 U.S.C. 4001 *et seq.*); and the National Flood Insurance Reform Act of 1994 (Pub. L. 103-325, 42 U.S.C. 4001). FMA under 44 CFR part 77 (October 1, 2021) (previously located at 44 CFR part 79) provides funding for measures taken to reduce or eliminate the long-term risk of flood damage to buildings, manufactured homes, and other structures insured under the National Flood Insurance Program (NFIP).

The BRIC program is authorized by section 203 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), as amended (Pub. L. 93-288, 42 U.S.C. 5133). The BRIC program seeks to fund effective and innovative activities that will reduce risk, increase resilience, and serve as a catalyst to encourage the whole community to invest in and adopt hazard mitigation policies. BRIC is designed to promote a national culture of preparedness and public safety by encouraging investments to protect our communities and infrastructure and strengthen our national hazard mitigation capabilities to foster resilience.

BRIC DTA provides non-financial direct technical assistance as authorized by section 203 of the Stafford Act (42 U.S.C. 5133) to eligible communities, helping them reduce risks from natural disasters and build resilience. The program offers hands-on guidance for developing and implementing mitigation projects, navigating funding opportunities, and strengthening local capability and capacity to address natural hazards. BRIC DTA focuses on ensuring communities can access resources and expertise to enhance disaster preparedness and resilience.

The PDM grant program is authorized under section 203 of the Stafford Act (42 U.S.C. 5133). PDM makes Federal funds available to State, local, Tribal, and territorial governments to plan for and implement sustainable cost-effective