1983, originally held by Wockhardt Bio AG, and currently held by Pharmobedient Consulting.

DEXAMETHASONE is indicated for:

(1) *Endocrine disorders:* primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance); congenital adrenal hyperplasia; nonsuppurative thyroiditis; and hypercalcemia associated with cancer.

(2) *Rheumatic disorders:* as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis; acute and subacute bursitis; acute nonspecific tenosynovitis; acute gouty arthritis; post-traumatic osteoarthritis; synovitis of osteoarthritis; and epicondylitis.

(3) *Collagen diseases:* during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus and acute rheumatic carditis.

(4) *Dermatologic diseases:* pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, mycosis fungoides, severe psoriasis, and severe seborrheic dermatitis.

(5) *Allergic states:* control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment such as seasonal or perennial allergic rhinitis, bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, and drug hypersensitivity reactions.

(6) *Ophthalmic diseases:* severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as allergic conjunctivitis, keratitis, allergic corneal marginal ulcers, herpes zoster ophthalmicus, iritis and iridocyclitis, chorioretinitis, anterior segment inflammation, diffuse posterior uveitis and choroiditis, optic neuritis, and sympathetic ophthalmia.

(7) *Respiratory diseases:* symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, and aspiration pneumonitis.

(8) *Hematologic disorders:* idiopathic thrombocytopenic purpura in adults, secondary thrombocytopenia in adults, acquired (autoimmune) hemolytic anemia, erythroblastopenia (red blood cell anemia), and congenital (erythroid) hypoplastic anemia.

(9) *Neoplastic diseases:* for palliative management of leukemia and lymphomas in adults, and acute leukemia of childhood.

(10) *Edematous states:* to induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

(11) *Gastrointestinal diseases:* to tide the patient over a critical period of the disease in ulcerative colitis and regional enteritis.

(12) *Miscellaneous:* tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, and trichinosis with neurologic or myocardial involvement.

(13) Diagnostic testing of adrenocortical hyperfunction.

In a letter dated November 16, 2021, Wockhardt Bio AG notified FDA that DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated February 4, 2026 (Docket No. FDA–2026–P–1306), under 21 CFR 10.30, requesting that the Agency determine whether DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 mL, was 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 DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 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 DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 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. 2026–08939 Filed 5–5–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4588]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; OTARMENI (lunsotogene parvec-cwha)

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 OTARMENI (lunsotogene parvec-cwha), approved April 23, 2026, manufactured by Regeneron Pharmaceuticals, 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 OTARMENI (lunsotogene parvec-cwha), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a priority review voucher. OTARMENI (lunsotogene parvec-cwha) is indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.

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 OTARMENI (lunsotogene parvec-cwha), 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. 2026–08913 Filed 5–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Psychosocial Influences on Healthy Development.

Date: June 4, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kimberly L. Houston, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–4902, *Kimberly.Houston@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Par Panel; Enhancing Mechanistic Research on Precision Probiotic Therapies.

Date: June 4, 2026.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dayadevi Jirage, Ph.D. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867–5309, *jiragedb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training: Career Development

Date: June 4, 2026.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Delia Tang, MD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (240) 276–6456, *tangd@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Clinical Neuroimmunology and Brain Tumors.

Date: June 4, 2026.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–3101, *dario.dieguez@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Skeletal Development, Repair and Regeneration.

Date: June 9, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vanessa Dawn Sherk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801C, Bethesda, MD 20892, (301) 594–3218, *sherkv2@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

Date: June 9–10, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, *sarita.sastry@nih.gov.*

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Interspecies Microbial Interactions and Infections Study Section.

Date: June 10, 2026.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irene Ramos Lopez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (301) 480–4891, *irene.ramoslopez@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Translational Cancer Research SPORE P50.

Date: June 11, 2026.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Amr M. Ghaleb, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812, Bethesda, MD 20892, (301) 443–5851, *amr.ghaleb@nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Prokaryotic Cell and Molecular Biology Study Section.

Date: June 11, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.