ESTIMATED BURDEN—ONGOING REQUESTS—Continued

Instrument	Number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Annual burden (in hours)
Office of Refugee Resettlement Refugee Microenterprise Development (MED) Program Pre-Monitoring Questionnaire (PMQ)	15	1	5	75
Total Annual Ongoing Burden	2,110			4,112

Based on the past 3 years and with a goal to reduce burden moving forward the estimated annual burden for potential new requests is 31 percent less than the currently approved umbrella generic.

ESTIMATED BURDEN—FUTURE REQUESTS

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
New Program Monitoring Forms	2,000	3	1.85	11,100

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: This generic is related to and will be of use to all ACF program offices that award federal funds (*e.g.,* grants, cooperative agreements) and monitor activities related to funding. Each individual program use will be related to a specific statutory authority.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–08935 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–P–1306]

Determination That DEXAMETHASONE (Dexamethasone) Elixir, 0.5 Milligrams/5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 or Agency) has determined that DEXAMETHASONE (dexamethasone) elixir, 0.5 milligrams (mg)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness.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: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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.

DEXAMETHASONE (dexamethasone) elixir, 0.5 mg/5 mL, is the subject of ANDA 088254, approved on July 27,

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