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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

DECADRON (dexamethasone sodium phosphate) solution/drops, EQ 0.1 percent phosphate, is the subject of NDA 011984, held by Merck and Co., Inc., and initially approved on September 2, 1959. DECADRON is indicated for the treatment of the following conditions: Ophthalmic: Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical or thermal burns, or penetration of foreign bodies; and Otic: Steroid responsive inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and nonpurulent infective otitis externa when the hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

DECADRON (dexamethasone sodium phosphate) solution/drops, EQ 0.1 percent phosphate, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Odin Pharmaceuticals, LLC, submitted a citizen petition dated August 30, 2024 (Docket No. FDA–2024–P–4158), under 21 CFR 10.30, requesting that the Agency determine whether DECADRON (dexamethasone sodium phosphate) solution/drops, EQ 0.1 percent phosphate, 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 DECADRON (dexamethasone sodium phosphate) solution/drops, EQ 0.1 percent phosphate, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DECADRON (dexamethasone sodium phosphate) solution/drops, EQ 0.1 percent phosphate, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DECADRON (dexamethasone sodium phosphate), solution/drops, EQ 0.1 percent phosphate, 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 DECADRON (dexamethasone sodium phosphate) solution/drops, EQ 0.1 percent phosphate, 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.

Dated: March 31, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–06046 Filed 4–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–4293]

Determination That NASCOBAL (Cyanocobalamin) Nasal Spray, 0.5 Milligram/Spray, 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 NASCOBAL (cyanocobalamin) nasal spray, 0.5 milligram (mg)/spray, 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: Helen Ryan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 301–796–1328, *helen.ryan@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.

NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, is the subject of NDA 021642, held by Endo Operations Ltd., and initially approved on January 31, 2005. NASCOBAL is a vitamin B12 indicated for vitamin B12 maintenance therapy in adult patients with pernicious anemia who are in remission following intramuscular vitamin B12 therapy and who have no nervous system involvement; treatment of adult patients with dietary, drug-induced, or malabsorption-related vitamin B12 deficiency not due to pernicious anemia; and prevention of vitamin B12 deficiency in adult patients with vitamin B12 requirements in excess of normal.

In a letter dated July 26, 2024, Endo Operations Ltd. notified FDA that NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Robert van Osdel submitted a citizen petition dated September 7, 2024 (Docket No. FDA–2024–P–4293), under 21 CFR 10.30, requesting that the Agency determine whether NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, 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 NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, 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 NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, 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.

Dated: March 31, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–06043 Filed 4–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0129]

Electronic Study Data Submission; Data Standards; Clinical Data Interchange Standards Consortium Dataset-JavaScript Object Notation; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is exploring Clinical Data Interchange Standards Consortium (CDISC) Dataset-JavaScript Object Notation (Dataset-JSON) version 1.1 as a new exchange standard, with the long-term potential to replace Statistical Analysis System (SAS) version 5 XPORT Transport Format (XPT), for submission of electronic study data to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). FDA is requesting comments on whether to accept Dataset-JSON to exchange electronic study data as part of regulatory applications in the future. In particular, FDA is requesting feedback on the risks and benefits of industry adopting Dataset-JSON as a new exchange standard for submitting electronic study data to FDA and any integration challenges with existing tools and systems.

DATES: Either electronic or written comments must be submitted by June 9, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and