ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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21 CFR 10.30, requesting that the Agency determine whether NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, was withdrawn from sale for reasons of safety or effectiveness.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have at this time, FDA has determined under § 314.161 that NASCOBAL (cyanocobalamin) nasal spray, 0.5 mg/spray, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness.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]

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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

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–N–0129 for ''Electronic Study Data Submission; Data Standards; Clinical Data Interchange Standards Consortium Dataset-JavaScript Object Notation; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, *Chenoa.Conley@fda.hhs.gov,* 10903 New Hampshire Ave., Bldg. 32, Rm. 3158, Silver Spring, MD 20993–0002, 301–796–0035; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, *James.Myers@fda.hhs.gov,* 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Background

In recent years, JSON has become a universal format within the global web and is the preferred choice for a variety of publicly available web services. While JSON is a standard for data exchange, Dataset-JSON is a JSON-based schema specifically designed for exchanging tabular datasets that is based on CDISC Dataset-JSON version 1.0 with enhancements, including smaller file sizes, additional metadata, and simpler processing. CDISC Dataset-JSON supports file and Application Programming Interface based data exchange, is widely supported across technologies, and can link to Define-XML for additional metadata.

In 2022, the Agency completed a high-level assessment on the costs and benefits of a potential transition to a modern data exchange format. Options evaluated included SAS version 8 XPT, Extensible Markup Language, and JSON. The assessment findings were based on a weighted evaluation of Agency requirements, which indicated JSON as the optimal modern format with the potential to serve as a replacement to SAS version 5 XPT. From September 2023 to April 2024, FDA collaborated with the CDISC and Pharmaceutical Users Software Exchange (PHUSE) to execute a pilot that tested the feasibility of using CDISC Dataset-JSON as a transport format for study data submitted with regulatory applications. The CDISC–PHUSE pilot results demonstrated that CDISC Dataset-JSON has the potential to serve as a transport file for study data. For additional information on the CDISC–PHUSE pilot titled ''Dataset-JSON as an Alternative Transport Format for Regulatory Submissions: Final Pilot Report'' can be found at: *https://phuse.s3.eu-central-1.amazonaws.com/Deliverables/Optimizing+the+Use+of+Data+Standards/WP-88+Dataset-JSON+Report.pdf.*

JSON has become ubiquitous on the web and is the most commonly used format to represent Health Level Seven/Fast Healthcare Interoperability Resource, the standard specified for the use of electronic healthcare records by the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology.

Through this notice, FDA is requesting comments from industry on adoption risks and benefits and any integration challenges with existing tools and systems associated with the use of Dataset-JSON to exchange electronic study data as part of regulatory applications. A future transition to Dataset-JSON is being considered to improve the Agency's ability to receive and process regulatory submission information and ensure alignment with the FDA's Data Modernization Action Plan. More information about the FDA Data Modernization Action Plan can be found at: *https://www.fda.gov/about-fda/reports/data-modernization-action-plan.* FDA understands that any potential change to the current regulatory submission requirements could have a significant impact on the industry. As such, the Agency is open to future engagements with industry and vendors through further testing initiatives utilizing CDISC Dataset-JSON.

If the Agency makes the decision to adopt Dataset-JSON as the new format for electronic submissions in the future, the Agency intends to do so in accordance with the final guidance titled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-standardized-study-data*), which implements electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in new drug applications, abbreviated new drug applications, biologics license applications, and investigational new drug applications submitted to CDER or CBER by specifying the format for electronic submissions.

Dated: March 28, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–06051 Filed 4–8–25; 8:45 am]

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