TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 203665	Fludeoxyglucose F18 injectable, 20–500 millicurie (mCi)/mL	SOFIE Co. dba SOFIE, 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166.
ANDA 204403	Rivastigmine extended-release film, 4.6 mg/24 hours (hr), 9.5 mg/24 hr, and 13.3 mg/24 hr.	Alvogen, Inc., 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 204530	Sodium Fluoride F18 injectable, 10–200 mCi/mL	B&H Consulting Services, Inc., U.S. Agent for Hot Shots NM, LLC, 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 204541	Sodium Fluoride F18 injectable, 10–200 mCi/mL	Essential Isotopes LLC, 1513 Research Park Dr., Columbia, MO 65211.
ANDA 204667	Ammonia N 13 injectable, 18.8 mCi-188 mCi/5 mL (3.75–37.5 mCi/mL).	SOFIE Co. dba SOFIE.
ANDA 204860	Prochlorperazine Edisylate injectable, EQ 5 mg base/mL	Nexus Pharmaceuticals, LLC.
ANDA 205901	Telmisartan tablets, 20 mg, 40 mg, and 80 mg	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd., Unit V, 1035 Centennial Ave., Piscataway, NJ 08854.
ANDA 206071	Methocarbamol solution, 1 gram (gm)/10 mL (100 mg/mL)	Navinta LLC.
ANDA 206468	Dicyclomine HCl injectable, 10 mg/mL	Nexus Pharmaceuticals, LLC.
ANDA 206561	Indomethacin Sodium injectable, EQ 1 mg base/vial	Navinta LLC.
ANDA 206681	Oxacillin Sodium injectable, EQ 1 gm base/vial, and EQ 2 gm base/vial.	Piramal Critical Care, Inc., 3950 Schelden Circle, Bethlehem, PA 18017.
ANDA 206724	Budesonide delayed-release capsule, 3 mg	Syneos Health, LLC, U.S. Agent for Natco Pharma Limited, 1030 Sync St., Morrisville, NC 27560.
ANDA 206760	Oxacillin Sodium injectable, EQ 10 gm base/vial	Piramal Critical Care, Inc.
ANDA 208679	Fludeoxyglucose F 18 injectable, 20–300 mCi/mL	Memorial Sloan Kettering Cancer Center, 1275 York Ave., New York, NY 10065.
ANDA 208878	Midazolam HCl injectable, EQ 5 mg base/mL	Fresenius Kabi USA, LLC.
ANDA 210356	Haloperidol injectable, EQ 5 mg base/mL	Do.
ANDA–210774	Acyclovir ointment, 5%	Apotex Corp., U.S. Agent for Apotex Inc., 2400 North Commerce Pkwy., Suite 400, Weston, FL 33326.
ANDA 211794	Acyclovir ointment, 5%	Cipla USA, Inc., U.S. Agent for Cipla Limited.
ANDA 212775	Azelastine HCl spray, metered, 0.2055 mg/spray	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 213247	Metformin HCl extended-release tablets, 500 mg, and 1 gm	Elity, LLC, U.S. Agent for TWi Pharmaceuticals, Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027.
ANDA 213394	Metformin HCl extended-release tablets, 500 mg, and 1 gm	PHL US Pharma LLC, U.S. Agent for Utopic Pharmaceuticals Inc., 3396 Kipling St., Palo Alto, CA 94306.
ANDA 213823	Bortezomib injectable, 3.5 mg/vial	Baxter Healthcare Corp.
ANDA 214436	Pemetrexed Disodium powder, EQ 100 mg base/vial, and EQ 500 mg base/vial.	Do.
ANDA 218354	Edaravone solution, 30 mg/100 mL (0.3 mg/mL)	Long Grove Pharmaceuticals LLC, 9450 W Bryn Mawr Ave., Suite 200, Rosemont, IL 60018.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of October 23, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on October 23, 2025 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18453 Filed 9–23–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–3959]

Approval of Previously Withdrawn New Drug Application for WELLCOVORIN (Leucovorin Calcium) Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing approval of the previously withdrawn new drug application (NDA) for Wellcovorin (leucovorin calcium) tablets, equivalent to (EQ) 5 milligrams (mg) base and EQ 25 mg base. FDA is initiating this action on the basis of new data and is required to publish notice of approval of an NDA for which the Agency had previously withdrawn approval.

FOR FURTHER INFORMATION CONTACT: Harold Sano, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4355, Silver Spring, MD 20993–0002, 301–796–2429, *Harold.Sano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing approval of the previously withdrawn NDA 018342 for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base in accordance with 21 CFR 314.160, which provides, in relevant part, that FDA may, on the basis of new data, approve an application for which it had previously withdrawn approval.

Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, are the subject of NDA 018342, initially approved on July 8, 1983, and held by GlaxoSmithKline (GSK). The most recently approved labeling for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, stated that the drug products were indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists. In the **Federal Register** of September 22, 1999, FDA announced that it was withdrawing approval of NDA 018342 after GSK notified the Agency that Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, were no longer marketed and requested that the approval of the application be withdrawn under 21 CFR 314.150(c). Subsequently, in the **Federal**

Register of April 28, 2017, FDA announced its determination that Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, were not withdrawn from sale for reasons of safety or effectiveness under 21 CFR 314.161.

Under 21 CFR 314.160, FDA, on its own initiative or upon request of an applicant, may, on the basis of new data, approve an application or abbreviated application which it had previously refused, suspended, or withdrawn approval. With respect to leucovorin calcium tablets, FDA has conducted a systematic analysis of literature published between 2009–2024 and has determined that the information supports a finding that orally administered leucovorin calcium tablets improve certain symptoms in adults and pediatric patients with cerebral folate deficiency (CFD). Published case reports provided patient-level data on over 40 patients, including both adults and pediatric patients, with genetically confirmed CFD due to variants in the FOLR1 gene who were treated with oral leucovorin. Patients had heterogenous clinical symptoms that included global developmental delays with autistic features and psychomotor regression, intractable epilepsy, and cerebellar ataxia. In some patients, leucovorin dosing was titrated based on levels of 5-methyltetrahydrofolate (5-MTHF) in the cerebrospinal fluid (CSF) or symptoms. Clinical outcomes were compared to the known natural history of CFD due to variants in the FOLR1 gene as historic control. The majority of patients demonstrated substantial improvement of symptoms of CFD that would not be expected when compared to the natural history of CFD due to FOLR1 gene variants. In addition, we reviewed mechanistic data that demonstrated a normalization in CSF 5-MTHF levels in 80% of patients who had CSF samples available for analysis following administration of leucovorin. We note that CFD has been reported in patients with neuropsychiatric symptoms, including autistic features, and detectable serum autoantibodies to the folate receptor alpha; however, data on the use of leucovorin is limited in this population and additional studies are needed.

Subsequent to the approval of NDA 018342 for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, that is being announced in this Notice, FDA intends to request that GSK submit a prior approval supplemental NDA to revise the prescribing information for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, to include the essential scientific information needed for the safe and effective use of these drug products for the treatment of CFD in adults and pediatric patients.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18510 Filed 9–22–25; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0795]

Computer Software Assurance for Production and Quality System Software; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Computer Software Assurance for Production and Quality System Software.'' FDA is issuing this guidance to provide recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. FDA believes that these recommendations will help foster the adoption and use of innovative technologies that promote patient access to high-quality medical devices and help manufacturers to keep pace with the dynamic, rapidly changing technology landscape, while promoting compliance with laws and regulations implemented by FDA.

DATES: The announcement of the guidance is published in the **Federal Register** on September 24, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2022–D–0795 for ''Computer Software Assurance for Production and Quality System Software.'' Received comments 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