4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0707]

GlaxoSmithKline; Withdrawal of Approval of a New Drug Application for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, held by GlaxoSmithKline, LLC, 2020 Walnut Street, Philadelphia, PA 19104 (GSK). GSK notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-3601, druginfo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: GSK has informed FDA that for Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, is no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). GSK has also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of NDA 018342, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Approval of the entire application is withdrawn, including any strengths and dosage forms inadvertently missing from this notice. Introduction or delivery for introduction into interstate commerce of Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, without an approved NDA violates sections 505(a) and 301 (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Any Wellcovorin (leucovorin calcium) tablets, EQ 5 mg base and EQ 25 mg base, that is in inventory on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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.

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