4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4310]

Allergan Pharmaceuticals International, LTD; Withdrawal of Approval of a New Drug Application for LO MINASTRIN FE

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 LO MINASTRIN FE (ethinyl estradiol tablets, 0.01 milligrams (mg); ethinyl estradiol and norethindrone acetate tablets, 0.01 mg/1mg; and ferrous fumarate tablets, 75 mg), held by Allergan Pharmaceuticals International, LTD, c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940 (Allergan). Allergan notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: Allergan has informed FDA that LO MINASTRIN FE (ethinyl estradiol tablets, 0.01 mg; ethinyl estradiol and norethindrone acetate tablets, 0.01

mg/1mg; and ferrous fumarate tablets, 75 mg) is no longer marketed and has requested that FDA withdraw approval of NDA 204654 under the process in § 314.150(c) (21 CFR 314.150(c)). Allergan has also, by its request, waived its 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Therefore, approval of NDA 204654, and all amendments and supplements thereto, is hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Approval of the entire application is withdrawn, including any strengths and dosage forms inadvertently missing from this notice.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 a product without an approved new drug application violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Any Lo Minastrin Fe that is in inventory on **[INSERT DATE 30 DAYS AFTER 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.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-23309 Filed: 10/24/2019 8:45 am; Publication Date: 10/25/2019]