



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0644]

Eli Lilly and Company; Withdrawal of Approval of SARAFEM (Fluoxetine Hydrochloride) Capsules, Equivalent to 10 Milligrams Base and Equivalent to 20 Milligrams Base, Including the Premenstrual Dysphoric Disorder Indication Approved Under New Drug Application 018936

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of SARAFEM (fluoxetine hydrochloride (HCl)) capsules, equivalent to (EQ) 10 milligrams (mg) base and EQ 20 mg base, including the premenstrual dysphoric disorder (PMDD) indication, approved under new drug application (NDA) 018936. This NDA is held by Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285 (Lilly). Lilly notified the Agency in writing that SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, indicated for the treatment of PMDD, was no longer marketed and requested that the approval of SARAFEM (fluoxetine HCl) capsules, including the PMDD indication, be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 29, 1987, FDA approved NDA 018936 for PROZAC (fluoxetine HCl) capsules, EQ 20 mg base, for major depressive disorder. On July 6, 2000, FDA approved a supplement to NDA 018936 for SARAFEM (fluoxetine HCl) capsules,

EQ 10 mg base and EQ 20 mg base, indicated for the treatment of PMDD. SARAFEM (fluoxetine HCl) capsules are only approved for the PMDD indication. SARAFEM (fluoxetine HCl) capsules and PROZAC (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, were marketed by Lilly under the same NDA with distinct labeling, including distinct Prescribing Information, carton and container labels, and labeling for patients and caregivers.

On June 10, 2010, Lilly informed FDA that it had discontinued marketing of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base. On August 4, 2023, Lilly requested, in writing, that FDA withdraw approval of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, including the PMDD indication, under § 314.150(c) (21 CFR 314.150(c)). Lilly also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, including the PMDD indication approved under NDA 018936, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Withdrawal of approval of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, including the PMDD indication approved under NDA 018936, does not affect approval of PROZAC (fluoxetine HCl) capsules, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base, and EQ 60 mg base, or any other indication approved under NDA 018936.

Introduction or delivery for introduction into interstate commerce of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 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)).

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.