4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0002]

Abbott Laboratories, et al.; Withdrawal of Approval of Four New Drug Applications and Two Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new drug applications (NDAs) and two abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective Date: [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications pursuant to the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have 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.

Application No.	Drug	Applicant
NDA 019080	ProSom (estazolam) Tablets, 1 milligram (mg) and 2 mg	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064
NDA 020195	Fentanyl Oralet (fentanyl citrate) Troche/Lozenge, Equivalent to (EQ) 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, and EQ 0.4 mg base	Cephalon, Inc., 41 Moores Rd., Frazer, PA 19355
NDA 021726	Niravam (alprazolam) Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg	UCB, Inc., 1950 Lake Park Dr., Building 2100, Smyrna, GA 30080
ANDA 084287	Methyltestosterone Tablets USP , 10 mg	Impax Laboratories, Inc., 31047 Genstar Rd., Hayward, CA 94544
ANDA 084310	Methyltestosterone Tablets USP, 25 mg	Do.
NDA 205208	Desvenlafaxine Fumarate Extended-Release Tablets, EQ 50 mg base and EQ 100 mg base	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on the date that this notice becomes effective (see the DATES section) 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: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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