4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2156]

Ferring Pharmaceuticals, Inc.; Withdrawal of Approval of Two Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of two abbreviated new drug applications (ANDAs) from Ferring Pharmaceuticals, Inc. (Ferring). Ferring 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ferring has informed FDA that the drug products listed in the table are no longer marketed and has requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). Ferring 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.

Application No.	Drug	Applicant
ANDA 073598	Menotropins (follicle-stimulating hormone (FSH)/luteinizing hormone (LH)) for Injection, 75 international units (IU)/75 IU per vial	Ferring Pharmaceuticals, Inc., 100 Interpace Pkwy., Parsippany, NJ 07054
ANDA 073599	Menotropins (FSH/LH) for Injection, 150 IU/150 IU per vial	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are 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: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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