4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2194]

Novartis Pharmaceuticals Corporation, et al.; Withdrawal of Approval of Five New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five new drug applications (NDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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 under 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 020831	Foradil Aerolizer (formoterol fumarate) Powder, 0.012 milligram (mg)/inhalation	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936
NDA 022504	Axiron (testosterone) Transdermal Metered Solution, 30 mg/1.5 milliliter (mL) actuation	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 050585	Rocephin (ceftriaxone sodium) for Injection, equivalent to (EQ) 10 gram (g) base/vial, EQ 250 mg base/vial (IV/IM), EQ 500 mg base/vial (IV/IM), EQ 1 g base/vial (IV/IM), EQ 2 g base/vial (IV/IM), EQ 500 mg base/vial, N/A; N/A, 1% (Rocephin kit), EQ 1 g base/vial, N/A; N/A, 1% (Rocephin kit)	Hoffmann-La Roche, Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080
NDA 050624	Rocephin (ceftriaxone sodium) with Dextrose in Plastic Container Injection, EQ 10 mg base/mL, EQ 20 mg base/mL, and EQ 40 mg base/mL	Do.
NDA 202763	Testosterone Gel, 25 mg/2.5 g packet, 50 mg/5 g packet	ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623

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 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.
[FR Doc. 2018-13293 Filed: 6/20/2018 8:45 am; Publication Date: 6/21/2018]