4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4416]

Allied Pharma, Inc., et al.; Withdrawal of Approval of Nine 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 nine abbreviated new drug applications (ANDAs) from multiple applicants. The applicants 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: The applicants 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 described 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
ANDA 073079	Loperamide Hydrochloride (HCl) Oral Solution, 1 milligram (mg)/5 milliliters	Allied Pharma, Inc., 20 Corrielle St., Fords, NJ 08863
ANDA 076741	Ibuprofen Tablets USP, 100 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788
ANDA 080210	Lidocaine Ointment, 5%	Belmora, LLC, 2231 Crystal Dr., #1000, Arlington, VA 22202
ANDA 085497	Phendimetrazine Tartrate Tablets, 35 mg	Virtus Pharmaceuticals, LLC, 2050 Cabot Blvd. West, 2nd Floor, Langhorne, PA 19047
ANDA 085695	Phendimetrazine Tartrate Capsules, 35 mg	Do.
ANDA 086365	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 086399	Theolair (theophylline) Tablets, 125 mg and 250 mg	Medicis Pharmaceutical Corp., c/o Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 087378	Phendimetrazine Tartrate Extended-Release Capsules, 105 mg	Virtus Pharmaceuticals, LLC
ANDA 202030	Bromfenac Sodium Ophthalmic Solution, Equivalent to 0.09% Acid	Amring Pharmaceuticals, Inc., 1235 Westlakes Dr., Suite 205, Berwyn, PA 19312

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: December 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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