DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1866]

Wockhardt Ltd., 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@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 040533	Bethanechol Chloride Tablets, 10 milligrams (mg)	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC, 6451 Main St., Morton Grove, IL 60053.
ANDA 040534	Bethanechol Chloride Tablets, 25 mg	Do.
ANDA 075015	Acyclovir Sodium for Injection, Equivalent to (EQ) 500 mg base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 075773	Pamidronate Disodium for Injection, 30 mg/vial, and 90 mg/vial.	Do.
ANDA 076206	Calcitriol Injection, 0.001 mg/milliliter (mL)	Rockwell Medical, Inc., 30142 S. Wixom Rd., Wixom, MI 48393.
ANDA 076207	Pamidronate Disodium Injection, 30 mg/10 mL (3 mg/mL) and 90 mg/mL (9 mg/mL).	Fresenius Kabi USA, LLC.
ANDA 077788	Albuterol Sulfate Syrup, EQ 2 mg base/5 mL	VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771.
ANDA 077990	Zolpidem Tartrate Tablets, 5 mg and 10 mg	Carlsbad Technology, Inc., U.S. Agent for Yung Shin Pharmaceutical Industrial Co., Ltd., 4761 Tara Ct., West Bloomfield, MI 48323.
ANDA 202410	Donepezil Hydrochloride Tablets, 23 mg	Hisun Pharmaceutical (Hangzhou) Co., Ltd., U.S. Agent, Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd., 2nd floor, Bridgewater, NJ 08807.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. 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 November 9, 2020 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: October 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1867]

Novartis Pharmaceuticals Corp., et al.; Withdrawal of Approval of 13 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 13 new drug applications (NDAs) 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 November 9, 2020.

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: 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.