



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5608]

Wockhardt Limited, et al.; Withdrawal of Approval of 28 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 28 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: 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](mailto: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 040732	Phenytoin Sodium Capsules, 100 milligrams (mg) (Extended)	Wockhardt Limited, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053
ANDA 065230	Ceftriaxone for Injection, Equivalent to (EQ) 250 mg base/vial; EQ 500 mg base/vial; EQ 1 gram (g) base/vial; EQ 2 g base/vial	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 065231	Ceftriaxone for Injection, EQ 1 g base/vial; EQ 2 g base/vial Piggy Back	Do.
ANDA 065290	Cefotaxime Sodium for Injection, EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 065292	Cefotaxime Sodium for Injection, EQ 10 g base/vial Pharmacy Bulk Package	Do.
ANDA 065293	Cefotaxime Sodium for Injection, EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 065312	Cefoxitin for Injection, EQ 10 g base/vial Pharmacy Bulk Package	Do.
ANDA 065313	Cefoxitin for Injection, EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 065369	Cefepime Hydrochloride (HCl) for Injection, EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 065483	Cefuroxime Sodium for Injection, EQ 750 mg base/vial; EQ 1.5 g base/vial	Do.
ANDA 065484	Cefuroxime Sodium for Injection, EQ 7.5 g base/vial Pharmacy Bulk Package	Do.
ANDA 065503	Cefuroxime Sodium for Injection, EQ 1.5 g base/vial	Do.
ANDA 075250	Prednisolone Sodium Phosphate Oral Solution, EQ 15 mg base/5 milliliters (mL)	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807

ANDA 075618	Acetaminophen, Butalbital, Caffeine, and Codeine Phosphate Capsules, 325 mg, 50 mg, 40 mg, and 30 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 090375	Ampicillin and Sulbactam for Injection, EQ 1 g base/vial and EQ 500 mg base/vial; EQ 2 g base/vial and EQ 1 g base/vial	Hospira, Inc.
ANDA 090646	Ampicillin and Sulbactam for Injection, EQ 10 g base/vial and EQ 5 g base/vial	Do.
ANDA 090653	Ampicillin and Sulbactam for Injection, EQ 1 g base/vial and EQ 500 mg base/vial; EQ 2 g base/vial and EQ 1 g base/vial	Do.
ANDA 090825	Imipenem and Cilastatin for Injection, EQ 250 mg base/vial and 250 mg base/vial; EQ 500 mg base/vial and 500 mg/vial	Do.
ANDA 090940	Meropenem for Injection, 500 mg/vial, and 1 g/vial	Do.
ANDA 091007	Imipenem and Cilastatin for Injection, EQ 500 mg base/vial and 500 mg/vial	Do.
ANDA 202268	Cefepime HCl for Injection, EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 202563	Ceftriaxone for Injection, EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 202864	Ampicillin Sodium for Injection, EQ 250 mg base/vial; EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 202865	Ampicillin Sodium for Injection, EQ 10 g base/vial Pharmacy Bulk Package	Do.
ANDA 203132	Cefotaxime Sodium for Injection, EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 204879	Pyridoxine HCl Injection, 100 mg/mL	Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103
ANDA 206062	Doxorubicin HCl for Injection, USP, 20 mg/vial	Hisun Pharmaceutical Hangzhou Co., LTD, 200 Crossing Blvd., 2nd

		Floor, Bridgewater, NJ 08807
ANDA 206195	Daunorubicin HCl for Injection, EQ 20 mg base/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*]. Approval of each entire application is withdrawn, including any strengths or products 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 [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: February 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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