4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5715]

Watson Laboratories, Inc., and Barr Laboratories, Inc., Subsidiaries of Teva Pharmaceuticals USA, Inc.; Withdrawal of Approval of 54 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 54 abbreviated new drug applications (ANDAs) from two 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 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 abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1

Application No.	Drug	Applicant
ANDA 061717	Doxycycline Hyclate Capsules USP, Equivalent to (EQ) 50 milligrams (mg) base and EQ 100 mg base	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 062087	Erythromycin Estolate Capsules USP, EQ 250 mg base	Do.
ANDA 062318	Gentamicin Injection USP, EQ 10 mg base/milliliter (mL) and EQ 40 mg base/mL	Do.
ANDA 062816	Ampicillin for Injection USP, EQ 125 mg base/vial, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial	Do.
ANDA 062994	Ampicillin for Injection USP, EQ 10 g base/vial	Do.
ANDA 062999	Erythromycin Delayed-Release Tablets USP, 500 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 064036	Cefuroxime for Injection USP, EQ 7.5 g base/vial	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070296	Diazepam Injection USP, 5 mg/mL	Do.
ANDA 070412	Furosemide Tablets USP, 20 mg	Do.
ANDA 070435	Ibuprofen Tablets USP, 200 mg	Do.
ANDA 070436	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 070437	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 070449	Furosemide Tablets USP, 20 mg	Do.
ANDA 070450	Furosemide Tablets USP, 40 mg	Do.
ANDA 070515	Tolazamide Tablets USP, 500 mg	Do.
ANDA 070528	Furosemide Tablets USP, 80 mg	Do.
ANDA 071238	Doxepin Hydrochloride (HCl) Capsules USP, EQ 50 mg base	Do.
ANDA 071547	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 072397	Diazepam Injection USP, 5 mg/mL	Do.
ANDA 072407	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072602	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072630	Albuterol Tablets USP, EQ 4 mg base	Do.
ANDA 072825	Baclofen Tablets USP, 20 mg	Do.
ANDA 073013	Metaproterenol Sulfate Tablets USP, 10 mg	Do.
ANDA 073445	Meperidine HCl Injection USP, 100 mg/mL	Do.
ANDA 074025	Guanabenz Acetate Tablets USP, EQ 4 mg base and EQ 8 mg base	Do.
ANDA 074114	Dobutamine Injection USP, EQ 12.5 mg base/mL	Do.
ANDA 074163	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074287	Piroxicam Capsules USP, 10 mg and 20 mg	Do.

Application No.	Drug	Applicant
ANDA 074303	Pentamidine Isethionate for Injection, 300 mg/vial	Do.
ANDA 074437	Pindolol Tablets USP, 5 mg and 10 mg	Do.
ANDA 074456	Alprazolam Tablets USP, 0.25 mg, 0.5 mg, and 1 mg	Do.
ANDA 077643	Topiramate Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg	Do.
ANDA 080728	Diphenhydramine HCl Capsules USP, 25 mg	Do.
ANDA 080968	Dexamethasone Tablets USP, 0.75 mg	Do.
ANDA 081040	Chlorzoxazone Tablets USP, 500 mg	Do.
ANDA 081149	Hydroxyzine HCl Tablets USP, 10 mg	Do.
ANDA 081189	Hydrochlorothiazide Tablets USP, 25 mg	Do.
ANDA 081216	Estropipate Tablets USP, 6 mg	Do.
ANDA 083232	Hydrochlorothiazide Tablets USP, 50 mg	Do.
ANDA 085720	Meprobamate Tablets USP, 200 mg	Do.
ANDA 085721	Meprobamate Tablets USP, 400 mg	Do.
ANDA 085778	Hydroxyzine HCl Injection USP, 25 mg/mL	Do.
ANDA 086096	Chlorpheniramine Maleate Injection USP, 10 mg/mL	Do.
ANDA 086189	Ergoloid Mesylates Sublingual Tablets USP, 0.5 mg	Do.
ANDA 086598	Nandrolone Decanoate Injection USP, 100 mg/mL	Do.
ANDA 086795	Chlorothiazide Tablets USP, 250 mg	Do.
ANDA 087183	Ergoloid Mesylates Sublingual Tablets USP, 1 mg	Do.
ANDA 087296	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 087521	Chlorthalidone Tablets USP, 50 mg	Do.
ANDA 087772	Prednisone Tablets USP, 50 mg	Do.
ANDA 087979	Chloroquine Phosphate Tablets USP, EQ 150 mg base	Do.
ANDA 088030	Chloroquine Phosphate Tablets USP, EQ 300 mg base	Do.
ANDA 089042	Procainamide HCl Extended-Release Tablets USP, 750 mg	Do.

Therefore, approval of the applications listed in table 1, 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 table 1 that are in inventory on the date that this notice becomes effective (see

the DATES section) 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 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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