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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0839]

Ranbaxy Laboratories Limited; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) held by Ranbaxy Laboratories Ltd., c/o Ranbaxy Inc. (Ranbaxy), 600 College Rd. East, Princeton, NJ 08540. The drug products are no longer marketed, and Ranbaxy has requested that the approval of the applications be withdrawn.

DATES: Effective date: [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The drug products listed in table 1 in this document are no longer marketed, and Ranbaxy has requested that FDA withdraw approval of the applications. The company has also waived its opportunity for a hearing. Ranbaxy requested withdrawal of approval under a Consent Decree of Permanent Injunction (Decree) entered in United States v. Ranbaxy Laboratories, Ltd. et al., JFM 12-250 (D. Md.) on January 26, 2012. The Decree specifies that Ranbaxy must never submit another application to FDA for these withdrawn drug products and must never transfer these ANDAs to a third party.

Table 1

Application No.	Drug
064155	Cefaclor for Oral Suspension USP, 375 milligrams (mg)/5 milliliters (mL)
064156	Cefaclor Capsules USP, 250 mg and 500 mg
064164	Cefaclor for Oral Suspension USP, 250 mg/5 mL
064165	Cefaclor for Oral Suspension USP, 187 mg/5 mL
064166	Cefaclor for Oral Suspension USP, 125 mg/5 mL
065015	Cefadroxil Capsules USP, 500 mg
065018	Cefadroxil Tablets USP, 1 gram
065043	Cefuroxime Axetil Tablets USP, 125 mg, 250 mg, and 500 mg
065080	Dispermox (amoxicillin tablets for oral suspension USP), 200 mg and 400 mg
065092	Raniclor (cefaclor chewable tablets USP), 125 mg, 187 mg, 250 mg, and 375 mg
065100	Panixine Disperdose (cephalexin tablets for oral suspension USP), 125 mg and 250 mg
065159	Dispermox (amoxicillin tablets for oral suspension USP), 600 mg
065198	Cefprozil Tablets USP, 250 mg and 500 mg
065202	Cefprozil for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL
075226	Etodolac Tablets USP, 400 mg and 500 mg
076021	Terazosin Hydrochloride (HCl) Capsules, 1 mg, 2 mg, 5 mg, and 10 mg
076220	Ofloxacin Tablets, 200 mg, 300 mg, and 400 mg
076386	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg

Application No.	Drug
076413	Metformin HCl Extended-Release Tablets USP, 500 mg
076445	Pravastatin Sodium Tablets USP, 10 mg, 20 mg, 40 mg, and 80 mg
076457	Ganciclovir Capsules, 250 mg and 500 mg
076580	Fosinopril Sodium Tablets USP, 10 mg, 20 mg, and 40 mg
076875	Glimepiride Tablets USP, 1 mg, 2 mg, 4 mg, and 8 mg
076951	Nitrofurantoin/Nitrofurantoin Macrocrystalline Capsules, 75 mg/25 mg
077211	Metformin HCl Extended-Release Tablets USP, 750 mg
077327	Zidovudine Tablets USP, 300 mg
078849	Ramipril Capsules, 5 mg and 10 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [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 FD&C Act (21 U.S.C. 331(a) and (d)).

Dated: August 15, 2012.

Douglas C. Throckmorton,

Deputy Director,

Center for Drug Evaluation and Research.

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