4161-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2338]

Apotex, Inc.; Withdrawal of Approval of 31 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of 31 abbreviated new drug applications (ANDAs) held by Apotex, Inc. (Apotex). Apotex, through its U.S. agent, has requested withdrawal of these applications and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

FDA approved the following ANDAs on the dates indicated in the table, for the conditions of use found in the reference listed drug for each application:

ANDA	Date of Approval	Name of Drug Product
040774	October 3, 2007	Hydrochlorothiazide Tablets USP, 25 milligrams (mg) and 50 mg
065507	July 13, 2011	Azithromycin Tablets, 250 mg
065508	July 13, 2011	Azithromycin Tablets, 600 mg
065509	July 13, 2011	Azithromycin Tablets, 500 mg
078389	May 16, 2008	Hydrochlorothiazide Capsules, 12.5 mg
078841	June 2, 2011	Donepezil Hydrochloride Tablets, 5 mg and 10 mg
090150	October 6, 2010	Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg, 100 mg/12.5mg, and 100 mg/25 mg

090419	April 22, 2009	Mycophenolate Mofetil Capsules, 250 mg
090463	August 30, 2010	Perindopril Erbumine Tablets, 2 mg, 4 mg, and 8 mg
090499	April 22, 2009	Mycophenolate Mofetil Tablets, 500 mg
090790	October 6, 2010	Losartan Potassium Tablets USP, 25 mg, 50 mg, and 100 mg
091260	August 25, 2011	Cevimeline Hydrochloride Capsules, 30 mg
091373	April 22, 2011	Naratriptan Tablets USP, 1 mg and 2.5 mg
091379	November 6, 2012	Sildenafil Citrate Tablets, 20 mg
200164	September 25, 2012	Tolterodine Tartrate Tablets, 1 mg and 2 mg
200832	October 15, 2012	Irbesartan Tablets USP, 75 mg, 150 mg, and 300 mg
200878	April 20, 2012	Verapamil Hydrochloride Extended-Release Tablets USP, 120 mg, 180 mg, and 240 mg
201294	August 3, 2012	Montelukast Sodium Tablets, 10 mg
201503	March 8, 2013	Cabergoline Tablets, 0.5 mg
201505	October 15, 2012	Irbesartan and Hydrochlorothiazide Tablets USP, 150 mg/12.5 mg, and 300 mg/12.5 mg
201508	August 3, 2012	Montelukast Sodium Chewable Tablets, 4 mg and 5 mg
201950	September 12, 2013	Rasagiline Mesylate Tablets, 0.5 mg and 1 mg
202078	May 14, 2013	Zolmitriptan Tablets, 2.5 mg and 5 mg
202079	January 10, 2014	Candesartan Cilexetil Tablets, 4 mg, 8 mg, 16 mg, and 32 mg
202244	December 31, 2012	Rizatriptan Benzoate Tablets, 5 mg and 10 mg
202476	May 14, 2013	Zolmitriptan Orally Disintegrating Tablets, 2.5 mg and 5 mg
202477	July 1, 2013	Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg and 10
202884	December 4, 2012	Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16 mg/12.5 mg, 32 mg/12.5 mg, and 32 mg/25 mg
203021	May 22, 2012	Nevirapine Tablets USP, 200 mg
203026	March 21, 2013	Valsartan and Hydrochlorothiazide Tablets USP, 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg
205258	April 3, 2014	Nevirapine Extended-Release Tablets, 400 mg

However, after these drugs were approved, FDA became aware of concerns involving material manufactured at two Apotex facilities, at least one of which was named in each of these applications. The facilities involved were Apotex Private Research Ltd. (Federal Employer Identification (FEI) number: 3006076314) and Apotex Pharmachem India Private Ltd. (FEI: 3005466325). The application numbers for the impacted ANDAs are listed above. In January 2018, Apotex requested withdrawal of the above ANDAs and waived its opportunity for a hearing. FDA interprets this withdrawal request as a request under § 314.150(d) (21 CFR 314.150(d)).

Therefore, for the reasons discussed above, and pursuant to Apotex's request, FDA is withdrawing approval of the ANDAs in the table above, and all amendments and supplements thereto, under § 314.150(d). In each case, approval of the entire application is withdrawn, including any approved strengths inadvertently missing from the table. Distribution of the products listed in the table above in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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