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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5851]

Teva Branded Pharmaceutical Products R&D, Inc., et al.; Withdrawal of Approval of 12 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 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 application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Table1.--NDAs for Which Approval Is Withdrawn

Application No.	Drug	Applicant
NDA 009388	Diamox IV (acetazolamide) Injectable, Equivalent to (EQ) 500 milligrams (mg) base per vial	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Parkway, West Chester, PA 19380

NDA 012836	Persantine (dipyridamole) Tablets, 25mg, 50mg, and 75mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, P.O. Box 368, Ridgefield, CT 06877
NDA 018817	Calan (verapamil hydrochloride (HCl)) Tablets, 40 mg, 80 mg, 120 mg, and 160 mg	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001
NDA 021743	Tarceva (erlotinib HCl) Tablets, EQ 25 mg base, EQ 100 mg base, and EQ 150 mg base	OSI Pharmaceuticals, LLC, 2375 Waterview Dr., Northbrook, IL 60062
NDA 021785	Invirase (saquinavir mesylate) Tablets, EQ 500 mg base	Hoffmann-La Roche, Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080
NDA 021937	Atripla (efavirenz, emtricitabine, and tenofovir disoproxil fumarate) Tablets, 600 mg/200 mg/300 mg	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404
NDA 022383	Arcapta Neohaler (indacaterol maleate) Powder for Inhalation, EQ 75 micrograms base	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936
NDA 204412	Delzicol (mesalamine), Delayed-Release Capsules, 400 mg	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064
NDA 210875	Kynmobi (apomorphine HCl) Sublingual Film, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg	Sumitomo Pharma America, Inc.., 84 Waterford Dr., Marlborough, MA 01752
NDA 211172	Tegsedi (inotersen sodium) Solution for Injection, EQ 284 mg base/1.5 mL	Akcea Therapeutics, Inc., 2850 Gazelle Ct., Carlsbad, CA 92010
NDA 212640	Exservan (riluzole) Oral Film, 50 mg	Aquestive Therapeutics, 30 Technology Dr., Warren, NJ 07059
NDA 213426	Seglentis (celecoxib and tramadol HCl) 56 mg; 44 mg	Kowa Pharmaceuticals America, Inc., 530 Industrial Park Blvd., Montgomery, AL 36117

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*]. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug

products that are listed in table 1 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: January 6, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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