4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0598]

Teva Women's Health, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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

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 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
NDA 007883	Antabuse (disulfiram) Tablets, 250 milligrams (mg) and 500 mg	Teva Women's Health, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355
NDA 011324	Sinografin (diatrizoate meglumine and iodipadmide meglumine) Injection, 52.7%/26.8%	Bracco Diagnostic Inc., 259 Prospect Plains Rd., Bldg. H, Monroe Township, NJ 08831
NDA 018932	ReVia (naltrexone hydrochloride) Tablets, 50 mg	Teva Women's Health, Inc.
NDA 019880	Paraplatin (carboplatin) Injection, 50 mg/vial, 150 mg/vial, and 450 mg/vial	Corden Pharma Latina S.p.A., c/o Clinipace, Inc., 4840 Pearl East Circle, Suite 201E, Boulder, CO 80301
NDA 020261	Lescol (fluvastatin sodium) Capsules, 20 mg and 40 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936-1080
NDA 020452	Paraplatin (carboplatin) Injection in multiple dose vials, 50 mg/5 milliliters (mL), 150 mg/15 mL, 450 mg/45 mL, and 600 mg/60 mL	Corden Pharma Latina S.p.A.
NDA 021431	Campral (acamprosate calcium) Delayed-Release Tablets, 333 mg	Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940
NDA 021551	Halflytely and Bisacodyl Tablet Bowel Prep Kit (polyethylene glycol 3350, potassium chloride, sodium bicarbonate, and sodium chloride powder for oral solution, 210 grams (g) /0.74 g/2.86 g/5.6 g; bisacodyl delayed-release tablet, 5 mg)	Braintree Laboratories, Inc., 60 Columbian St. West, P.O. Box 850929, Braintree, MA 02185
NDA 021823	Actonel with Calcium (risedronate sodium tablets, 35 mg; calcium carbonate tablets USP, equivalent to 500 mg base)	Warner Chilcott Co., LLC., 100 Enterprise Dr., Rockaway, NJ 07866
NDA 021905	Valtropine (somatropin) for Injection, 5 mg/vial	LG Chem, Ltd., c/o Parexel International, LLC., 4600 East-West Highway, Suite 350, Bethesda, MD 20814
NDA 022396	Dyloject (diclofenac sodium) Injection, 37.5 mg/mL	Javelin Pharmaceuticals, Inc., c/o Hospira, Inc., 275 North Field Dr., Dept. 0389, HI-3S, Lake Forest, IL 60045
NDA 050619	Mycostatin (nystatin) Pastilles, 200,000 Units	Delcor Asset Corp., c/o Mylan, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504-4310
NDA 050739	Omnicef (cefdinir) Capsules, 300 mg	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064
NDA 050749	Omnicef (cefdinir) Oral Suspension, 125 mg/5 mL and 250 mg/5 mL	Do.
NDA 050757	PrevPAC (amoxicillin capsules USP, 500 mg; clarithromycin tablets USP, 500 mg; and lansoprazole delayed-release capsules, 30 mg)	Takeda Pharmaceuticals U.S.A., Inc., One Takeda Parkway, Deerfield, IL 60015
NDA 202356	Docetaxel Injection, 20 mg/2 mL, 80 mg/8 mL, 130 mg/13 mL, and 200 mg/20 mL	Pfizer Inc., 235 East 42nd St., New York, NY 10017

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*]**. The drug product strengths listed in the

table include all strengths FDA has identified as being previously approved under these NDAs. In each case, approval of the entire application is withdrawn, including any strengths 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: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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