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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1020]

Aurolife Pharma, LLC, et al.; 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 approval of 31 abbreviated new drug applications (ANDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: 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, Trang.Tran@fda.hhs.gov.

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 described 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
ANDA 070470	Disopyramide Phosphate Capsules USP,	Aurolife Pharma, LLC, 279 Princeton

	Equivalent to (EQ) 100 milligrams (mg) base	Hightstown Rd., East Windsor, NJ 08520
ANDA 070471	Disopyramide Phosphate Capsules USP, EQ 150 mg base	Do.
ANDA 070531	Clofibrate Capsules USP, 500 mg	Upsher-Smith Laboratories, LLC, 301 South Cherokee St., Denver, CO 80223
ANDA 070797	Chlorpheniramine Maleate Extended-Release Capsules USP, 12 mg	Aurolife Pharma, LLC
ANDA 070956	Diazepam Tablets USP, 10 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233
ANDA 071128	Haloperidol Tablets USP, 0.5 mg	Cycle Pharmaceuticals, Ltd., c/o Mapi USA, Inc., 2343 Alexandria Dr., Suite 100, Lexington, KY 40504
ANDA 071129	Haloperidol Tablets USP, 1 mg	Do.
ANDA 071133	Haloperidol Tablets USP, 20 mg	Do.
ANDA 072394	Fenoprofen Calcium Capsules USP, EQ 200 mg base	Aurolife Pharma, LLC
ANDA 072395	Fenoprofen Calcium Capsules USP, EQ 300 mg base	Do.
ANDA 072396	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072484	Trazodone Hydrochloride (HCl) Tablets USP, 50 mg	Do.
ANDA 074024	Ketoprofen Capsules, 50 mg and 75 mg	Do.
ANDA 074448	Flurbiprofen Tablets USP, 50 mg and 100 mg	Do.
ANDA 078300	Pamidronate Disodium for Injection USP, 30 mg/vial and 90 mg/vial	Mustafa Nevzat Ilac San. A.S. (MN Pharmaceuticals), c/o Sagent Pharmaceuticals, Inc., 1901 North Roselle Rd., suite 450, Schaumburg, IL 60195
ANDA 080655	Meprobamate Tablets USP, 400 mg	Aurolife Pharma, LLC
ANDA 083234	Glutethimide Tablets, 500 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr. North, Maple Grove, MN 55369
ANDA 084156	Pentobarbital Sodium Capsules, 100 mg	Warner-Lambert Company, 201 Tabor Rd., Morris Plains, NJ 07950
ANDA 084674	Aminophylline Tables USP, 100 mg	Halsey Drug Co., Inc.
ANDA 085628	Sulfisoxazole Tablets USP, 500 mg	Aurolife Pharma, LLC
ANDA 085813	Prednisone Tablets USP, 20 mg	Do.
ANDA 085844	Sulfamethoxazole Tablets USP, 500 mg	Do.
ANDA 085925	Amitriptyline HCl Tablets USP, 50 mg	Halsey Drug Co., Inc.
ANDA 085926	Amitriptyline HCl Tablets USP, 75 mg	Do.
ANDA 085927	Amitriptyline HCl Tablets USP, 100 mg	Do.
ANDA 089057	Cyproheptadine HCl Tablets USP, 4 mg	Do.
ANDA 089117	Hydroxyzine HCl Tablets USP, 25 mg	Do.
ANDA 089894	Quinidine Gluconate Extended-Release Tablets USP, 324 mg	Aurolife Pharma, LLC
ANDA 089983	Prednisone Tablets USP, 10 mg	Do.
ANDA 089984	Prednisone Tablets USP, 50 mg	Do.
ANDA 208991	Piroxicam Capsules USP, 10 mg and 20 mg	Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., suite 201, Berlin, CT 06037

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*]. Approval of each entire application is withdrawn, including any strengths or products 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: April 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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