4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2040]

Liebel-Flarsheim Company LLC, et al.; Withdrawal of Approval of 11 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 11 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 016983	Conray 30 (iothalamate meglumine) Injection, 30%	Liebel-Flarsheim Co. LLC, 1034 South Brentwood Blvd., Suite 800, Richmond Heights, MO 63117
NDA 018972	Cordarone (amiodarone HCl) Tablets, 200 mg	Wyeth Pharmaceuticals LLC, P.O. Box 8299, Philadelphia, PA 19101-8299
NDA 019009	Maxair Inhaler (pirbuterol acetate inhalation aerosol), equivalent to (EQ) 0.2 mg base/inhalation	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NH 08807
NDA 019292	MD-76R (diatrizoate meglumine and diatrizoate sodium) Injection, 66%/10%	Liebel-Flarsheim Co. LLC
NDA 020014	Maxair Autohaler (pirbuterol acetate inhalation aerosol), EQ 0.2 mg base/inhalation	Bausch Health US, LLC
NDA 021041	DepoCyt (cytarabine liposome) Injection, 10 mg/mL	Pacira Pharmaceuticals, Inc., 5 Sylvan Way, Suite 300, Parsippany, NJ 07054
NDA 021338	Ionsys (fentanyl iontophoresis transdermal system), 40 mcg/activation	The Medicines Co., 8 Sylvan Way, Parsippany, NJ 07054
NDA 021575	Fosamax (alendronate sodium) Oral Solution, EQ 70 mg base/75 mL	Merck Sharp & Dohme Corp., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889-0100
NDA 022222	Ultresa (pancrelipase (amylase, lipase, protease)), Delayed-Release Capsules, 8,000 USP Units/4,000 USP Units/8,000 USP Units and 27,600 USP Units/13,800 USP Units/27,600 USP Units, and 41,400 USP Units/20,700 USP Units/41,400 USP Units, and 46,000 USP Units/23,000 USP Units/46,000 USP Units	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 022396	Dyloject (diclofenac sodium) Injection, 37.5 mg/mL	Javelin Pharmaceuticals, Inc., a subsidiary of Hospira Inc., 275 North Field Dr., Dept. 0392, Bldg. H1-3S, Lake Forest, IL 60045
NDA 203568	Kynamro (mipomersen sodium) Injection, 200 mg/mL	Kastle Therapeutics, 181 West Madison St., Suite 300, Chicago, IL 60602

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 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: June 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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