4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3761]

Sanofi-Aventis, U.S., LLC, et al.; Withdrawal of Approval of 20 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 20 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

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

NDA 006002	Aralen Hydrochloride (chloroquine hydrochloride (HCl)) Injection, Equivalent to (EQ) 40 milligram (mg) base/milliliter (mL); Aralen (chloroquine phosphate) Tablets, EQ 300 mg base	Sanofi-Aventis, U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807
NDA 008107	Leucovorin calcium for Injection USP, EQ 60 mg base/vial for solution, oral; EQ 3 mg base/mL injection; EQ 50 mg base/vial injection; EQ 100 mg base/vial injection; EQ 350 mg base/vial injection	Hospira Inc., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017
NDA 009321	Cholografin Meglumine (iodipamide meglumine) Injection, 10.3% and 52% (cholografin sodium, 20%)	Bracco Diagnostics, Inc., 259 Prospect Plains Rd., Monroe Township, NJ 08831
NDA 017566	Brevicon (ethinyl estradiol; norethindrone) Tablets, 0.035 mg/0.5 mg (21-Day Regimen)	Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612
NDA 018181	Mycelex (clotrimazole) Topical Solution, 1%	Bayer HealthCare LLC, 100 Bayer Blvd., 100 Bayer Rd., Pittsburgh, PA 15205
NDA 018182	Mycelex-7 (clotrimazole) Tablets, 100 mg	Do.
NDA 018183	Mycelex (clotrimazole) Topical Cream, 1%	Do.
NDA 018230	Mycelex-7 (clotrimazole) Topical Vaginal Cream, 1%	Do.
NDA 018856	D-Xylose (xylose) Powder, 25 grams (g)/bottle	Lyne Laboratories, 10 Burke Dr., Brockton, MA 02301
NDA 018874	Calcijex (calcitriol) Injection, 0.001 mg/mL and 0.002 mg/mL	AbbVie, Inc., 1 North Waukegan Rd., North Chicago, IL 60064
NDA 020214	Zemuron (rocronium bromide) Injection, 50 mg/5 mL (10 mg/mL); 10 mg/mL (10 mg/mL); 100 mg/10 mL (10 mg/mL)	Organon USA Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 020389	Mycelex-7 Combination Pack	Bayer HealthCare LLC

	(clotrimazole) Topical Vaginal Cream and Tablets, 1%, 100 mg	
NDA 020528	Mavik (trandolapril) Tablets, 1 mg, 2 mg, and 4 mg	AbbVie, Inc.
NDA 020738	Teveten (eprosartan mesylate) Tablets, 300 mg, 400 mg, and 600 mg	Do.
NDA 020863	Pletal (cilostazol) Tablets, 50 mg and 100 mg	Otsuka Pharmaceutical Development and Commercialization, Subsidiary of Otsuka Pharmaceutical Company, Ltd., 2440 Research Blvd., Rockville, MD 20850
NDA 021268	Teveten HCT (eprosartan mesylate and hydrochlorothiazide) Tablets, 600/12.5 mg and 600/25 mg	AbbVie, Inc.
NDA 021410	Avandamet (rosiglitazone maleate and metformin hydrochloride (HCl)) Tablets, 500 mg EQ 1 mg base; 500 mg EQ 2 mg base; 500 mg EQ 4 mg base; 1 g EQ 2 mg base; 1 g EQ 4 mg base	GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426
NDA 021511	Copegus (ribavirin) Tablets, 200 mg and 400 mg	Hoffmann La-Roche, Inc., Subsidiary of Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080
NDA 021700	Avandaryl (glimepiride and rosiglitazone maleate) Tablets, 1 mg/4 mg; 2 mg/4 mg; 2 mg/ 8 mg; 4 mg/4 mg; 4 mg/8 mg	SB Pharmco Puerto Rico Inc., Subsidiary of GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426
NDA 205123	Olysio (simeprevir sodium) Capsules, EQ 150 mg base	Janssen Pharmaceuticals, Inc., 1000 U.S. Rte. 202 South, Raritan, NJ 08869

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*]**. 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: October 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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