



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2272]

Hospira, Inc., et al.; Withdrawal of Approval of 27 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 27 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 008809	<p>M.V.I.-12 Adult (ascorbic acid, biotin, cyanocobalamin, dexpanthenol, ergocalciferol, folic acid, niacinamide, pyridoxine hydrochloride (HCl), riboflavin 5'-phosphate sodium, thiamine HCl, vitamin A, and vitamin E) Injection, 10 milligrams (mg)/milliliters (mL), 0.006 mg/mL, 0.5 micrograms (mcg)/mL, 1.5 mg/mL, 20 International Units (IU)/mL, 0.04 mg/mL, 4 mg/mL, 0.4 mg/mL, 0.36 mg/mL, 0.3 mg/mL, 330 Units/mL, and 1 IU/mL; and 20 mg/mL, 0.006 mg/mL, 0.05 mcg/mL, 1.5 mg/mL, 0.0005 mg/mL, 0.06 mg/mL, 4 mg/mL, 0.6 mg/mL, 0.36 mg/mL, 0.6 mg/mL, 0.1 mg/mL, and 1 mg/mL</p> <p>M.V.I.-12 Adult (ascorbic acid, biotin, cyanocobalamin, dexpanthenol, ergocalciferol, folic acid, niacinamide, pyridoxine HCl, riboflavin, thiamine HCl, vitamin A, and vitamin E) Injection, 20 mg/mL, 0.006 mg/mL, 0.5 mcg/mL, 1.5 mg/mL, 20 IU/mL, 0.6 mg/mL, 4 mg/mL, 0.4 mg/mL, 0.36 mg/mL, 0.6 mg/mL, 330 Units/mL, and 1 IU/mL</p>	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
NDA 017673	<p>Aminosyn (amino acids) Injection, 5% (5 grams (g)/100 mL), 7% (7 g/100 mL), 7% (pH6) (7 g/100 mL), 8.5% (8.5 g/100 mL), 8.5% (pH6) (8.5 g/100 mL), 10% (10 g/100 mL), and 10% (pH6) (10 g/100 mL)</p> <p>Aminosyn 8.5% With Electrolytes (amino acids, magnesium chloride, potassium chloride, sodium chloride, and sodium phosphate dibasic) Injection, 8.5% (8.5 g/100mL), 102 mg/100 mL, 487 mg/100 mL, 28 mg/100 mL, and 425 mg/100 mL</p> <p>Aminosyn 8.5% With Electrolytes (amino acids, magnesium chloride, potassium phosphate dibasic, and sodium chloride) Injection, 8.5% (8.5 g/100 mL), 102 mg/100 mL, 522 mg/100 mL,</p>	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045

Application No.	Drug	Applicant
	and 410 mg/100 mL	
NDA 017735	Modicon 28 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/0.5 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 017743	Brevicon 28-Day (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/0.5 mg	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 017789	Aminosyn 3.5% (amino acids) Injection, 3.5% (3.5 g/100 mL) Aminosyn 3.5% M (amino acids, magnesium acetate, phosphoric acid, potassium acetate, and sodium chloride) Injection, 3.5% (3.5 g/100 mL), 21 mg/100 mL, 40 mg/100 mL, 128 mg/100 mL, and 234 mg/100 mL Aminosyn 3.5% M (amino acids, magnesium acetate, potassium acetate, and sodium chloride) Injection, 3.5% (3.5 g/100 mL), 21 mg/100 mL, 128 mg/100 mL, and 234 mg/100 mL Aminosyn 7% With Electrolytes (amino acids, magnesium chloride, potassium phosphate dibasic, and sodium chloride) Injection, 7% (7 g/100 mL), 102 mg/100 mL, 410 mg/100 mL, and 522 mg/100 mL	ICU Medical, Inc.
NDA 018069	Vansil (oxamniquine) Capsules, 250 mg	Pfizer, Inc., 235 East 42 nd St., New York, NY 10017
NDA 018081	Depakene (valproic acid) Capsules, 250 mg	AbbVie, Inc., 1 North Waukegan Rd., North Chicago, IL 60064
NDA 018281	Tegretol (carbamazepine) Chewable Tablets, 100 mg	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936
NDA 018429	Aminosyn-RF 5.2% (amino acids) Injection, 5.2% (5.2 g/100 mL)	ICU Medical, Inc.
NDA 018704	Lopressor (metoprolol tartrate) Injection, 1 mg/mL	Novartis Pharmaceuticals Corp.

Application No.	Drug	Applicant
NDA 018876	<p>Potassium Chloride 5 milliequivalent (mEq) in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 74.5 mg/100 mL, and 300 mg/100 mL</p> <p>Potassium Chloride 5 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 149 mg/100 mL, and 300 mg/100 mL</p> <p>Potassium Chloride 10 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 74.5 mg/100 mL, and 300 mg/mL</p> <p>Potassium Chloride 10 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 149 mg/100 mL, and 300 mg/mL</p> <p>Potassium Chloride 15 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 224 mg/100 mL, and 300 mg/100 mL</p> <p>Potassium Chloride 20 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 298 mg/100 mL, and 300 mg/100 mL</p> <p>Potassium Chloride 20 mEq in Dextrose 5% in Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 149 mg/100 mL, and 300 mg/100 mL</p> <p>Potassium Chloride 30 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium</p>	Do.

Application No.	Drug	Applicant
	chloride, and sodium chloride) Injection, 5 g/100 mL, 224 mg/100 mL, and 300 mg/100 mL Potassium Chloride 40 mEq in Dextrose 5% and Sodium Chloride 0.3% in Plastic Container (dextrose, potassium chloride, and sodium chloride) Injection, 5 g/100 mL, 298 mg/100 mL, and 300 mg/100 mL	
NDA 018985	Ortho Novum 7/7/7 (ethinyl estradiol and norethindrone) (White) Tablets, 0.035 mg ethinyl estradiol and 0.5 mg norethindrone, (Light Peach) Tablets, 0.035 mg ethinyl estradiol and 0.75 mg norethindrone, (Peach) Tablets, 0.035 mg ethinyl estradiol and 1 mg norethindrone	Janssen Pharmaceuticals, Inc.
NDA 019029	Metronidazole Tablets, 250 mg	LNK International, Inc., 145 Ricefield Lane, Hauppauge, NY 11788
NDA 019374	Aminosyn-HBC 7% (amino acids) Injection, 7% (7 g/100 mL)	ICU Medical, Inc.
NDA 019435	Nix (permethrin) Topical Lotion, 1 %	GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, 184 Liberty Corner Rd., suite 2000, Warren, NJ 07059
NDA 019437	Aminosyn II M (amino acids, magnesium chloride, potassium chloride, sodium chloride, and sodium phosphate dibasic heptahydrate) Injection, 3.5% (3.5 g/100 mL), 30 mg/100 mL, 97 mg/100 mL, 120 mg/100 mL, and 49 mg/100 mL Aminosyn II With Electrolytes (amino acids, magnesium chloride, potassium chloride, potassium phosphate dibasic, and sodium chloride) Injection, 7% (7 g/100 mL), 102 mg/100 mL, 45 mg/100 mL, 522 mg/100 mL, and 410 mg/100 mL; 8.5% (8.5 g/100 mL), 102 mg/100 mL, 45 mg/100 mL, 522 mg/100 mL, and 410 mg/100 mL; and 10% (10 g/100 mL), 102 mg/100 mL, 45 mg/100 mL, 522 mg/100 mL, and 410 mg/100 mL Aminosyn II With Electrolytes (amino acids, magnesium chloride, potassium chloride,	Do.

Application No.	Drug	Applicant
	sodium chloride, and sodium phosphate dibasic) Injection, 8.5% (8.5 g/100 mL), 102 mg/100 mL, 492 mg/100 mL, 60 mg/100 mL, and 425 mg/100 mL	
NDA 019438	Aminosyn II 3.5% (amino acids) Injection, 3.5% (3.5 g/100 mL) Aminosyn II 5% (amino acids) Injection, 5% (5 g/100 mL) Aminosyn II 7% (amino acids) Injection, 7% (7 g/100 mL) Aminosyn II 8.5% (amino acids) Injection, 8.5% (8.5 g/100 mL) Aminosyn II 10% (amino acids) Injection, 10% (10 g/100 mL)	Do.
NDA 019653	Ortho-Cyclen-21 (ethinyl estradiol and norgestimate) Oral-21 Tablets, 0.035 mg/0.250 mg Ortho Cyclen-28 (ethinyl estradiol and norgestimate) Oral-28 Tablets, 0.035 mg/0.25 mg	Janssen Pharmaceuticals, Inc.
NDA 019894	Dextrose 50% in Plastic Container (dextrose) Injection, 50 g/100 mL	ICU Medical, Inc.
NDA 019916	Morphine Sulfate Injection, 1 mg/mL and 5 mg/mL	Do.
NDA 020593	Depacon (valproate sodium) Injection, Equivalent to (EQ) 100 mg base/mL	AbbVie, Inc.
NDA 020634	Levaquin (levofloxacin) Tablets, 250 mg, 500 mg, and 750 mg	Janssen Pharmaceuticals, Inc.
NDA 021241	Ortho Tri-Cyclen Lo (ethinyl estradiol and norgestimate) Oral-28 (White) Tablets, 0.025 mg ethinyl estradiol and 0.18 mg norgestimate; (Light Blue) Tablets, 0.025 mg ethinyl estradiol and 0.215 mg norgestimate; (Dark Blue) Tablets, 0.025 mg ethinyl estradiol and 0.250 mg norgestimate	Do.
NDA 206544	MorphaBond ER (morphine sulfate) Extended-Release Tablets, 15 mg, 30 mg, 60 mg, and 100 mg	Daiichi Sankyo, Inc., 211 Mount Airy Rd., Basking Ridge, NJ 07920
NDA 208399	Varubi (rolapitant HCl) Injectable Emulsion, EQ 166.5 mg base/92.5 mL (EQ 1.8 mg base/mL)	TerSera Therapeutics LLC, 520 Lake Cook Rd., suite 500, Deerfield, IL 60015
NDA 209203	Duzallo (allopurinol and lesinurad) Tablets, 200 mg/200 mg and 300 mg/200 mg	Ironwood Pharmaceuticals, Inc., 100 Summer St., suite 2300, Boston, MA 02110

Application No.	Drug	Applicant
NDA 210895	Welchol (colesevelam HCl) Chewable Bars, 3.75 g	Daiichi Sankyo, Inc.

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 and dosage forms 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: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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