meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for OPANA ER.

Based on postmarketing data, FDA later observed that there was a significant shift in the route of abuse from nasal to injection following the product's reformulation. Injection abuse of reformulated OPANA ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy). On June 8, 2017, FDA requested that Endo remove reformulated OPANA ER from the market based on its concern that the benefits of the drug may no longer outweigh its risks due to the public health consequences of abuse (see *https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse*). On July 6, 2017, Endo announced it would voluntarily remove reformulated OPANA ER from the market.

On October 3, 2017, Endo requested withdrawal of NDA 201655 for reformulated OPANA ER under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 201655 for reformulated OPANA ER (oxymorphone hydrochloride) extended-release tablets, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of reformulated OPANA ER into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28283 Filed 12–22–20; 8:45 am]

BILLING CODE 4164–01–P

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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 22, 2021.

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	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.	
	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..	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 017673	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).	
	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..	
	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, and 410 mg/100 mL..	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045.
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..	

Application No.	Drug	Applicant
	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 42nd 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.
NDA 018876	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.	
	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..	
	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..	
	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..	
	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..	
	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..	
	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..	
	Potassium Chloride 30 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..	
	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..	Do.
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, 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..	Do.
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.

Application No.	Drug	Applicant
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.
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 January 22, 2021. 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 January 22, 2021 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.

[FR Doc. 2020–28346 Filed 12–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID–19 Hoarding Prevention Measures; Correction of Extension Date

AGENCY: Office of the Secretary (OS), DHHS.

ACTION: Correction.

SUMMARY: This document updates the July 30, 2020, **Federal Register** Notice entitled ''Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID–19 Hoarding Prevention Measures,'' by revising the last sentence in the ''Summary'' section.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of Strategy, Policy, Planning, and Requirements, Suite 5440—O'Neill House Office Building, 200 C Street SW, Washington, DC 20201, (202) 260–0365.

SUPPLEMENTARY INFORMATION:

I. Correction of Errors

In FR Doc. 2020–16458 of July 30, 2020 (85 FR 45895–45897), make the following corrections:

On page 48596, first full column, **SUMMARY** section, change second to last sentence to ''This notice, issued on July 23, 2020, extends the March 25 Designation Notice to January 19, 2021.'' The expiration date, January 19, 2021 is not 120 days from the date of issuance so remove that reference.

Wilma Robinson,

Deputy Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020–28374 Filed 12–22–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public via NIH videocast. The URL link to this meeting is *https://videocast.nih.gov/watch=38984.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: January 27, 2021.

Open: 10:00 a.m. to 1:05 p.m.

Agenda: Report of the Director, NIDCR

Place: National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Room 662 Bethesda, MD 20892, (Virtual Meeting).

Closed: 1:20 p.m. to 2:00 p.m.

Agenda: Grant applications.

Place: National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Room 662 Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Room 662, Bethesda, MD 20892, 301–594–4805, *adombroski@nidcr.nih.gov.*

Any interested person may file written comments with the committee no later than 15 days after the meeting by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)