Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dragos Roman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5152, Silver Spring, MD 20993–0002, 301–796–1285; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition That Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies.'' This document is intended to provide guidance to sponsors on the evidence necessary to demonstrate the effectiveness of new drugs or new drug uses intended for slowly progressive, low-prevalence rare diseases that are associated with substrate deposition and are caused by single enzyme defects. This guidance applies only to those low-prevalence rare diseases with a well-characterized pathophysiology and in which changes in substrate deposition can be readily measured in relevant tissue(s).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on providing evidence of effectiveness for replacement or corrective therapies intended for slowly progressive, low-prevalence rare diseases with substrate deposition that results from single enzyme defects. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755. The collections of information for expedited programs in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf*) have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: July 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16036 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2493]

ICU Medical, Inc., 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 holders of the applications 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 August 27, 2018.

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 holders of the applications 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 020345	Aminosyn-HF (amino acids) Injection, 8%	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045.
ANDA 040723	Isosorbide Dinitrate Extended-Release Tablets USP, 40 milligrams (mg).	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 064062	Amphotericin B for Injection USP, 50 mg/vial	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 064200	Cefotaxime for Injection USP, Equivalent to (EQ) 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.

Application No.	Drug	Applicant
ANDA 064201	Cefotaxime for Injection USP, EQ 10 g base/vial and EQ 20 g base/vial.	Do.
ANDA 065251	Cefuroxime for Injection USP, EQ 75 g base/bag and EQ 225 g base/bag (Pharmacy Bulk Package).	Samson Medical Technologies, LLC, 2050 Springdale Rd., P.O. Box 2730, Suite 400, Cherry Hill, NJ 08034.
ANDA 070892	Metoclopramide Hydrochloride (HCl) Injection, EQ 10 mg base/2 milliliters (mL).	Norbrook Laboratories, Ltd., c/o Norbrook, Inc., 9401 Indian Creek Pkwy., Suite 680, Overland Park, KS 66210.
ANDA 075309	Ticlopidine HCl Tablets USP, 250 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 076797	Risperidone Oral Solution USP, 1 mg/mL	Precision Dose, Inc., 722 Progressive Lane, South Beloit, IL 61080.
ANDA 077656	Thrive (nicotine polacrilex) Gum USP (Chewable), EQ 4 mg base.	GlaxoSmithKline Consumer Healthcare, 184 Liberty Corner Rd., Suite 200, Warren, NJ 07059.
ANDA 077658	Thrive (nicotine polacrilex) Gum USP (Chewable), EQ 2 mg base.	Do.
ANDA 080188	Testosterone Propionate Injection USP, 25 mg/mL, 50 mg/mL, and 100 mg/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083398	Prednisolone Acetate Injectable Suspension, 25 mg/mL	Do.
ANDA 083764	Prednisolone Acetate Injectable Suspension, 50 mg/mL	Do.
ANDA 084072	Triamcinolone Diacetate Injection, 40 mg/mL	Do.
ANDA 084270	Triamcinolone Tablets USP, 4 mg	Do.
ANDA 084466	Reserpine and Hydrochlorothiazide Tablets, 0.125 mg/25 mg	Do.
ANDA 084604	Procainamide HCl Capsules, 250 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 085693	Phentermine HCl Tablets USP, 8 mg	Sandoz, Inc., 4700 Sandoz Dr., Wilson, NC 27893.
ANDA 085863	Theophylline Elixir, 80 mg/15 mL	Precision Dose, Inc.
ANDA 087185	Ergoloid Mesylates Sublingual Tablets USP, 1 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087770	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 088648	Methotrexate Injection USP, EQ 25 mg base/mL	Norbrook Laboratories, Ltd., c/o Norbrook, Inc.
ANDA 088928	Chlorzoxazone Tablets USP, 250 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 090663	Gemcitabine for Injection USP, EQ 200 mg base/vial and EQ 1 g base/vial.	Hameln RDS GmbH, c/o B&H Consulting Services, Inc., 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 091469	Vancomycin HCl for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 202390	Tramadol HCl Tablets USP, 50 mg	Accord Healthcare, Inc., 1009 Slater Rd., Suite 210–B, Durham, NC 27703.
ANDA 203506	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 204320	Olanzapine Orally Disintegrating Tablets USP, 5 mg, 10 mg, 15 mg, and 20 mg.	Ajanta Pharma, Ltd., c/o Ajanta Pharma USA, Inc., 440 U.S. Highway 22 East, One Grande Commons, Suite 150, Bridgewater, NJ 08807.
ANDA 204706	Olopatadine HCl Ophthalmic Solution USP, EQ 0.1% base	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242.
ANDA 207467	Nevirapine Extended-Release Tablets, 100 mg and 400 mg	Technology Organized, LLC, 9191 Point Replete Dr., Fort Belvoir, VA 22060.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 27, 2018. 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 August 27, 2018 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: July 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16037 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6380]

Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases.'' FDA does not expect to grant any additional orphan-drug designation to drugs for pediatric subpopulations of common diseases (*i.e.,* diseases or conditions with an overall prevalence of 200,000 or greater). This will help resolve an unintended loophole in the Pediatric Research Equity Act (PREA) orphan exemption process where a sponsor holding a pediatric-subpopulation designation can submit a marketing application for use of its drug