

collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; 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 601 have been approved under OMB control number 0910–0338; the collections of information in the guidance entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910–0765; and the collections of information in the guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants” have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either 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

Dated: July 5, 2018.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2018–14871 Filed 7–11–18; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2180]

Concordia Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 29 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 new drug applications (NDAs) 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longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 13, 2018.

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 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 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 011287	Kayexalate (sodium polystyrene sulfonate) Powder for Suspension, 453.6 gram (g)/bottle.	Concordia Pharmaceuticals, Inc., c/o Mapi USA, Inc., 2343 Alexandria Dr., Lexington, KY 40504.
NDA 012249	Librium (chlordiazepoxide hydrochloride (HCl)) Capsules, 5 milligram (mg), 10 mg, and 25 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 016211	Miochol (acetylcholine chloride) for Ophthalmic Solution, 20 mg/vial	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936.
NDA 018674	Metro I.V. (metronidazole) Injection, 500 mg/100 milliliter (mL)	B. Braun Medical, Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 018852	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg; 80 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 018854	Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg; 160 mg	Do.
NDA 018988	Vasocidin (prednisolone sodium phosphate and sulfacetamide sodium) Ophthalmic Solution, equivalent to (EQ) 0.23% phosphate/10%.	Novartis Pharmaceuticals Corp.
NDA 019844	Isolyte H in Dextrose 5% in Plastic Container Injection	B. Braun Medical, Inc.
NDA 019870	Isolyte M in Dextrose 5% in Plastic Container Injection	Do.
NDA 019964	Terazol 3 (terconazole) Vaginal Cream, 0.8%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 020000	Dextrose 5% in Ringer's in Plastic Container Injection	B. Braun Medical, Inc.
NDA 020393	Atrovent (ipratropium bromide) Nasal Spray, 0.021 mg/spray	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368.
NDA 020394	Atrovent (ipratropium bromide) Nasal Spray, 0.042 mg/spray	Do.
NDA 021180	Ortho Evra (ethinyl estradiol; norelgestromin) Transdermal Patch, 0.035 mg/24 h; 0.15 mg/24 h.	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, P.O. Box 300, Raritan, NJ 08869–0602.
NDA 021633	Femtrace (estradiol acetate) Tablets, 0.45 mg, 0.9 mg, and 1.8 mg	Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612.
NDA 022033	Luvox CR (fluvoxamine maleate) Extended-Release Capsules, 100 mg and 150 mg.	Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304.
NDA 022106	Doribax (doripenem) for Injection, 250 mg/vial and 500 mg/vial	Shionogi, Inc., 300 Campus Dr., Florham Park, NJ 07932.
NDA 022386	PrandiMet (metformin HCl; repaglinide) Tablets, 500mg; 1 mg and 500 mg; 2 mg.	Novo Nordisk, Inc., P.O. Box 846, Plainsboro, NJ 08536.
NDA 050201	Ophthocort (chloramphenicol, hydrocortisone acetate, polymyxin B sulfate) Ophthalmic Ointment USP, 10 mg/g; 5 mg/g; 10,000 units/g.	Parkedale Pharmaceuticals, Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 050344	Statrol (neomycin sulfate; polymyxin B sulfate) Ophthalmic Ointment, EQ 3.5 mg base/g; 10,000 units/g.	Alcon Laboratories, Inc., 6201 South Freeway, TC–45, Fort Worth, TX 76134.
NDA 050442	Vibramycin (doxycycline hyclate) Injection, EQ to 200 mg base/vial and EQ 100 mg base/vial.	Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 050497	Ticar (ticarcillin disodium) Injection, EQ 1 g base/vial, EQ 3 g base/vial, EQ 6 g base/vial, EQ 20 g base/vial, and EQ 30 g base/vial.	GlaxoSmithKline, 1250 Collegeville Rd., Collegeville, PA 19426.
NDA 050512	Duricef (cefadroxil monohydrate) USP Capsules, EQ 500 mg base and EQ 250 mg base.	Warner Chilcott Co., LLC, 100 Enterprise Dr., Rockaway, NJ 07866.
NDA 050527	Duricef (cefadroxil monohydrate) USP For Oral Suspension, EQ 125 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 500 mg base/5 mL.	Do.
NDA 050593	Eryc Sprinkles (erythromycin) Capsules, 125 mg	Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 050646	Ceptaz (ceftazidime) Injection, 500 mg/vial, 1 g/vial, 2 g/vial, and 10 g/vial.	GlaxoSmithKline.
NDA 050668	Lorabid (loracarbef) Capsules USP, 200 mg and 400 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 050792	Cefotaxime and Dextrose 2.4% in Plastic Container, EQ 2 g base, and Cefotaxime and Dextrose 3.9% in Plastic Container, EQ 1 g base.	B. Braun Medical, Inc.

Application No.	Drug	Applicant
NDA 050807	Epirubicin HCl for Injection, 50 mg/vial, 200 mg/vial	Hospira, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 13, 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 13, 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 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2018-D-2238]

Human Gene Therapy for Hemophilia; Draft 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 draft document entitled “Human Gene Therapy for Hemophilia; Draft Guidance for Industry.” The draft guidance document provides recommendations to stakeholders developing human gene therapy (GT) products for the treatment of hemophilia. The draft guidance provides recommendations on the clinical trial design and related development of coagulation factor VIII (hemophilia A) and IX (hemophilia B) activity assays, including how to address discrepancies in factor VIII and factor IX activity assays. The draft guidance also includes recommendations regarding preclinical considerations to support development of GT products for the treatment of hemophilia.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the

Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for Written/Paper Submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA 2018-D-2238 for “Human Gene Therapy for Hemophilia; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies, total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments, and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-