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Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Angela Moy, 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FDA is announcing the availability of a draft document entitled ''Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry.'' The draft guidance provides recommendations to stakeholders developing GT products for retinal disorders affecting adult and pediatric patients. These disorders vary in etiology, prevalence, diagnosis, and management, and include genetic as well as age-related diseases. These disorders manifest with central or peripheral visual impairment and often with progressive visual loss. The draft guidance focuses on issues specific to GT products for retinal disorders and provides recommendations related to product development, preclinical testing, and clinical trial design for such GT products.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy draft guidance documents entitled ''Human Gene Therapy for Hemophilia; Draft Guidance for Industry'' and ''Human Gene Therapy for Rare Diseases; Draft Guidance for Industry.''

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 ''Human Gene Therapy for Retinal Disorders.'' 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 draft guidance refers to previously approved collections of information 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 50 have been approved under OMB control number 0910–0755; the 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 211 have been approved under OMB control number 0910–0139; 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. 2018–14870 Filed 7–11–18; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–2258]**

### Human Gene Therapy for Rare Diseases; 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 Rare Diseases; Draft Guidance for Industry.'' The draft guidance document provides recommendations to stakeholders developing a human gene therapy (GT) product intended to treat a rare disease in adult and/or pediatric patients regarding the manufacturing, preclinical, and clinical trial design issues for all phases of the clinical development program. Such information is intended to assist sponsors in designing clinical development programs for such products, where there may be limited study population size and potential feasibility and safety issues as well as issues relating to the interpretability of bioactivity/efficacy outcomes that may be unique to rare diseases or to the nature of the GT product itself.

**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–2258 for ''Human Gene Therapy for Rare Diseases; 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 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jonathan McKnight, 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

The Orphan Drug Act of 1983 (Pub. L. 97–414) defines a rare disease as a disease or condition that affects fewer than 200,000 persons in the United States. Since most rare diseases have no approved therapies, there is a significant unmet need for effective treatments. However, developing safe and effective products to treat rare diseases can be challenging. For example, it may be more difficult to find and recruit such patients into clinical trials, and many rare diseases exhibit a number of variations or subtypes. Consequently, patients may have highly diverse clinical manifestations and rates of disease progression with unpredictable clinical courses. Despite these challenges, GT-related research and development continue to grow at a rapid rate, with several products advancing in clinical development.

FDA is announcing the availability of a document entitled ''Human Gene Therapy for Rare Diseases; Draft Guidance for Industry.'' The draft guidance provides recommendations to stakeholders developing a GT product intended to treat a rare disease in adult and/or pediatric patients regarding the manufacturing, preclinical, and clinical trial design issues for all phases of the clinical development program. Such information is intended to assist sponsors in designing clinical development programs for such products, where there may be limited study population size and potential feasibility and safety issues as well as issues relating to the interpretability of bioactivity/efficacy outcomes that may be unique to rare diseases or to the nature of the GT product itself.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy draft guidance documents entitled ''Human Gene Therapy for Hemophilia; Draft Guidance for Industry'' and ''Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry.''

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 ''Human Gene Therapy for Rare Diseases.'' 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 draft guidance refers to previously approved collections of information 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 50 have been approved under OMB control number 0910–0755; the

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]

**BILLING CODE 4164–01–P**

## 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. |