

| 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 | Sulfipyrazone 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. | Hamel 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

in the non-orphan adult population of that disease, get a pediatric-subpopulation designation for the pediatric subset of the disease, and, due to this designation, be exempt from conducting the pediatric studies normally required under PREA when seeking approval of the adult indication.

DATES: The announcement of the guidance is published in the **Federal Register** on July 27, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2017-D-6380 for "Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations

of Common Diseases." 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 this guidance to the Office of Orphan Products Development, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for

electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Aaron Friedman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5209, Silver Spring, MD 20993, 301-796-2989.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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." In the **Federal Register** of December 20, 2017 (82 FR 60402), FDA published a notice of availability for the draft guidance entitled "Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases," announcing that 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 over 200,000 in the United States). In the **Federal Register** of January 12, 2018 (83 FR 1619), FDA announced that it was extending the comment period for this draft guidance for an additional 30 days. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated December 2017. 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 in the non-orphan adult population of that disease, get a pediatric-subpopulation designation for the pediatric subset of the disease, and, due to this designation, be exempt from conducting the pediatric studies normally required under PREA when seeking approval of the adult indication. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on orphan designation of drugs and biologics for pediatric subpopulations of common 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. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Orphan> or <https://www.regulations.gov>.

Dated: July 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16027 Filed 7-26-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2478]

Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; 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 “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry.” The draft guidance document notifies blood establishments that collect blood and blood components that we have determined babesiosis to be a relevant transfusion-transmitted infection (RTTI) and provides recommendations for donor screening, donation testing, donor deferral, and product management to reduce the risk of transfusion-transmitted babesiosis (TTB). The recommendations contained in the guidance apply to the collection of blood and blood components, except Source Plasma.

DATES: Submit either electronic or written comments on the draft guidance by September 25, 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-2478 for “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; 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: Valerie A. Butler, 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 “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry.” The draft guidance document