Guidance for Industry.'' The guidance document provides blood establishments that collect blood and blood components with FDA's recommendations to reduce the risk of TTM. The recommendations contained in the guidance apply to the collection of Whole Blood and blood components, except Source Plasma. Blood establishments are not required to assess Source Plasma donors for malaria risk (see 21 CFR 630.15(b)(8)).

To address the urgent and immediate need for blood and blood components during the Coronavirus Disease 2019 (COVID–19) public health emergency, in April 2020 FDA issued revised recommendations to reduce the risk of TTM during the public health emergency. The recommendations in the April 2020 guidance were based on the Agency's evaluation of the available scientific and epidemiological data on malaria risk, and data on FDA-approved pathogen reduction devices. FDA stated in the April 2020 guidance that we expected implementation of the revised recommendations would not be associated with any adverse effect on the safety of the blood supply and that early implementation of the recommendations may help to address significant blood shortages that occurred as result of the COVID–19 public health emergency. Further, the guidance explained that we expected that the recommendations set forth in the revised guidance would continue to apply outside the context of the COVID–19 public health emergency, and that FDA would replace the April 2020 guidance with an updated guidance that incorporates any appropriate changes based on public comments and our experience with implementation. Although the April 2020 guidance stated that we intended to reissue the guidance within 60 days following the termination of the public health emergency, we are not delaying this issuance because the guidance represents our current thinking on the topic.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because the recommendations present a less burdensome policy for reducing the risk of transfusion-transmitted malaria that is consistent with public health, and interested parties have had the opportunity to comment on the recommendations in the April 2020 guidance. The recommendations, which are unchanged from the April 2020 guidance, will remain in effect outside of the context of the public health emergency related to COVID–19.

In the **Federal Register** of June 17, 2020 (85 FR 36598), FDA announced the availability of the final guidance entitled ''Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry'' dated April 2020. FDA received no comments on the final guidance.

The guidance represents the current thinking of FDA on ''Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338; 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116; and the collections of information for consignee and transfusion recipient physician notification have been approved under OMB control number 0910–0681.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26711 Filed 12–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3012]

Teva Branded Pharmaceutical Products R and D, Inc., et al.; Withdrawal of Approval of 35 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 35 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 9, 2023.

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, *Kimberly.Lehrfeld@fda.hhs.gov.*

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 006536	Urecholine (bethanechol chloride) Injection, 5 milligram (mg)/milliliter (mL) Urecholine (bethanechol chloride) Tablets, 5 mg, 10 mg, 25 mg, and 50 mg	Teva Branded Pharmaceutical Products R and D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 011707	Opana (oxymorphone hydrochloride (HCl)) Injection, 1 mg/mL and 1.5 mg/mL	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.

Application No.	Drug	Applicant
NDA 012209	Fluorouracil Injection, 500 mg/10 mL and 2.5 grams (g)/50 mL	Spectrum Pharmaceuticals, Inc., 157 Technology Dr., Irvine, CA 92618.
NDA 016772	Resectisol in plastic container (mannitol) Solution for Irrigation, 5 g/100 mL	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109–9341.
NDA 017354	Loestrin Fe 1/20 (ethinyl estradiol and norethindrone acetate) Tablets, 0.02 mg/1 mg	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 017355	Loestrin Fe 1.5/30 (ethinyl estradiol and norethindrone acetate) Tablets, 0.03 mg/1.5 mg)	Do.
NDA 017716	Ovcon-35 (ethinyl estradiol and norethindrone) 28-Day Tablets, 0.035 mg/0.4 mg	Warner Chilcott Co., LLC, c/o Warner Chilcott (U.S.) LLC, 100 Enterprise Dr., NJ 07866.
NDA 017875	Loestrin 1.5/30 (ethinyl estradiol and norethindrone acetate) 21-Day Tablets, 0.03 mg/1.5 mg.	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 017876	Loestrin 1/20 (ethinyl estradiol and norethindrone acetate) 21-Day Tablets, 0.02 mg/1 mg	Do.
NDA 018127	Ovcon-35 (ethinyl estradiol and norethindrone) 21-Day Tablets, 0.035 mg/0.4 mg	Warner Chilcott Co., LLC, c/o Warner Chilcott (U.S.) LLC.
NDA 018238	Micro-K (potassium chloride) Extended-release Capsules, 8 milliequivalents (mEQ) Micro-K 10 (potassium chloride) Extended-release Capsules, 10 mEQ	Nesher Pharmaceuticals USA, LLC, 13910 Saint Charles Rock Rd., Bridgeton, MO 63044.
NDA 018405	Aygestin (norethindrone acetate) Tablets, 5 mg	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 018603	Zovirax (acyclovir sodium) for Injection, equivalent to (EQ) 250 mg base/vial, EQ 500 mg base/vial, and EQ 1 g base/vial.	GlaxoSmithKline LLC, 2929 Walnut St., Suite 1700, Philadelphia, PA 19104.
NDA 018764	Metronidazole Tablets, 250 mg and 500 mg	Watson Laboratories, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Parsippany, NJ 07054.
NDA 018796	Pilopine HS (pilocarpine HCl) Ophthalmic Gel, 4%	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134–2099.
NDA 019211	Theophylline in Dextrose 5% in plastic containers, Injection, 4 mg/mL, 40 mg/100 mL, 80 mg/100 mL, 160 mg/100 mL, 200 mg/100 mL, 320 mg/100 mL, and 400 mg/100 mL.	Hospira, Inc., 275 North Field Dr., Bldg. HI–3S, Lake Forest, IL 60045.
NDA 019926	Hexalen (altretamine) Capsules, 50 mg	Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07611.
NDA 020130	Estrostep Fe (ethinyl estradiol and norethindrone acetate) Tablets, (white triangle) Tablets, 0.02 mg ethinyl estradiol and 1 mg norethindrone acetate; (white square) Tablets, 0.03 mg ethinyl estradiol and 1 mg norethindrone acetate; (white round) Tablets, 0.035 mg ethinyl estradiol and 1 mg norethindrone acetate. Estrostep 21 (ethinyl estradiol and norethindrone acetate) Tablets, (white triangle) Tablets, 0.02 mg ethinyl estradiol and 1 mg norethindrone acetate; (white square) Tablets, 0.03 mg ethinyl estradiol and 1 mg norethindrone acetate; and (white round) Tablets, 0.035 mg ethinyl estradiol and 1 mg norethindrone acetate.	Allergan Pharmaceuticals International Ltd., c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 020667	Mirapex (pramipexole dihydrocholoride) Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, 1.25 mg, and 1.5 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877.
NDA 020713	Mircette (ethinyl estradiol; desogestrel and ethinyl estradiol) Tablets, (yellow) Tablets, 0.01 mg ethinyl estradiol and (white) Tablets, 0.15 mg desogestrel and 0.02 mg ethinyl estradiol.	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 020903	Rebetol (ribavirin) Capsules, 200 mg Rebetol (ribavirin) Capsules, 200 mg (comarketed as Rebetron Combination Therapy with Interferon ALFA–2B, Recombinant (INTRON A)).	Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc., 126 East Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065.
NDA 021200	Zelnorm (tegaserod maleate) Tablets, EQ 2 mg base and EQ 6 mg base	Alfasigma USA, Inc., 550 Hills Dr., Suite 110B, Bedminster, NJ 07921.
NDA 021546	Rebetol (rivavirin) Oral Solution, 40 mg/mL	Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc.
NDA 021858	Boniva (ibandronate sodium) Injection, EQ 3 mg base/3 mL	Hoffmann La Roche Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080–4900.
NDA 021871	Loestrin 24 Fe (ethinyl estradiol and norethindrone acetate tablets, 0.02 mg/1mg; and ferrous fumarate tablets, 75 mg).	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 022266	Onsolis (fentanyl citrate) Buccal Film, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base, and EQ 1.2 mg base.	Adalvo Limited c/o Biotech Research Group, 3810 Gunn Highway, Tampa, FL 33618.
NDA 022569	Lazanda (fentanyl citrate) Nasal Spray, EQ 0.1 mg base, EQ 0.3 mg base, and EQ 0.4 mg base.	BTcP Pharma LLC, c/o West Therapeutic Development, LLC, 1033 Skokie Blvd., Suite 620, Northbrook, IL 60062.
NDA 040024	Dexferrum (ferric oxyhydroxide) Injection, EQ 50 mg iron/mL	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
NDA 202342	Esomeprazole Strontium Delayed-release Capsules, 24.65 mg and 49.3 mg	Belcher Pharmatech, LLC, 6911 Bryan Dairy Rd., Suite 220, Largo, FL 33777.
NDA 202788	Subsys (fentanyl) Sublingual Spray, 0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.2 mg, and 1.6 mg.	BTcP Pharma LLC, c/o West Therapeutic Development, LLC.
NDA 204325	Adzenys ER (amphetamine) Extended-release Oral Suspension, EQ 1.25 mg base/mL	Neos Therapeutics Brands, Inc., 2940 N Highway 360, Suite 400, Grand Prairie, TX 75050.
NDA 205637	Bunavail (buprenorphine HCl and naloxone HCl) Buccal Film, EQ 2.1 mg base/EQ 0.3 mg base, EQ 4.2 mg base/EQ 0.7 mg base, and EQ 6.3 mg base/EQ 1 mg base.	BioDelivery Sciences International, Inc., 4131 Park Lake Ave., Raleigh, NC 27612.
NDA 210045	Consensi (amlodipine besylate and celecoxib) Tablets, EQ 2.5 mg base/200 mg, EQ 5 mg base/200 mg, and EQ 10 mg base/200 mg.	Purple Biotech LTD, 2520 Meridian Pkwy., Suite 200, Durham, NC 27713.
NDA 211281	Pizensy (lactitol) Oral Solution, 10 g	Braintree Laboratories, Inc., 60 Columbian St. West, Braintree, MA 02184.
NDA 212038	Adhansia XR (methylphenidate HCl) Extended-release Capsules, 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, and 85 mg.	Purdue Pharma L.P., One Stamford Forum, 201 Tresser Blvd., Stamford, CT 06901–3431.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 9, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but 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 9, 2023 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 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26661 Filed 12–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0585]

Determination That NORFLEX (Orphenadrine Citrate) Injection, 30 Milligrams/Milliliter, and NORFLEX (Orphenadrine Citrate) Extended-Release Tablet, 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that NORFLEX (orphenadrine citrate) Injection, 30 milligrams (mg)/milliliter (mL), and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Anuj Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–2246, *Anuj.Shah@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, is the subject of NDA 013055, held by Pai Holdings LLC DBA Pharmaceutical Associates Inc., and initially approved on October 2, 1960. NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, is the subject of NDA 012157, held by Bausch Health US LLC, and initially approved on November 2, 1959. Both NORFLEX drug products are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions.

Both NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Odin Pharmaceuticals, LLC, submitted a citizen petition dated April 11, 2022 (Docket No. FDA–2022–P–0585), under 21 CFR 10.30, requesting that the Agency determine whether NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 100 mg extended-release tablet, that dosage form and strength has also been discontinued. On our own initiative, we have also determined whether that dosage form and strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NORFLEX (orphenadrine citrate) Injection, 30 mg/mL, and NORFLEX (orphenadrine citrate) Extended-Release Tablet, 100 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet