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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1037]

Fresenius USA, Inc., et al.; Withdrawal of Approval of 216 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 216 abbreviated new drug applications (ANDAs) from multiple holders of those ANDAs. The basis for the withdrawal is that these ANDA holders have repeatedly failed to submit required annual reports for those ANDAs.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: James Hanratty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-4718, James.Hanratty@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holders of an approved application to market a new drug for human use are required to submit annual reports to FDA concerning their approved application in accordance with §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). In the *Federal Register* of January 9, 2020 (85 FR 1160), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 249 ANDAs because the holders of those ANDAs had repeatedly failed to submit the required annual reports for those ANDAs ("Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 Abbreviated New

Drug Applications; Opportunity for a Hearing").[1] The holder of ANDA 085882, ANDA 086262, and ANDA 0866263 responded to the NOOH and requested a hearing. The remaining holders of those ANDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 constitutes an election by those holders of the ANDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their ANDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the 216 applications listed in table 1.

I. Annual Reports Submitted

In response to the NOOH, one firm requested a hearing and had previously submitted an annual report for each of its three ANDAs. Therefore, FDA rescinds its proposal to withdraw approval of the following three ANDAs:

Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920:

- ANDA 085882, DUVOID (bethanechol chloride) Tablets, 50 milligrams (mg)
- ANDA 086262, DUVOID (bethanechol chloride) Tablets, 10 mg
- ANDA 086263, DUVOID (bethanechol chloride) Tablets, 25 mg

Another three firms notified the Agency that they had submitted an annual report for each of its ANDAs listed in the NOOH. Therefore, FDA rescinds its proposal to withdraw approval of the following eight ANDAs:

Jerome Stevens Pharmaceuticals Inc., 60 DaVinci Dr., Bohemia, NY 11716:

- ANDA 062869, CEPHALEXIN Capsules USP, EQ 500 mg base
- ANDA 062870, CEPHALEXIN Capsules USP, EQ 250 mg base
- ANDA 074988, ASPIRIN, CAFFEINE, AND ORPHENADRINE CITRATE Tablets, 385 mg/30 mg/25 mg, and 770 mg/60 mg/50 mg
- ANDA 081145, ASPIRIN AND METHOCARBAMOL Tablets, 325 mg/400 mg

[1] 85 FR 1160, published on January 9, 2020, incorrectly listed 249 as the number of the ANDAs FDA proposed to withdrawal. 85 FR 1160 listed 248 ANDAs in the table included in the notice.

MIPS Cyclotron and Radiochemistry Facility, 1201 Welch Rd., Rm. PS049, Stanford, CA 94305:

- ANDA 204472, FLUDEOXYGLUCOSE F-18 Injection USP, 20-300 millicuries (mCi)/milliliters (mL)
- ANDA 204517, SODIUM FLUORIDE F-18 Injection, 10-200 mCi/mL
- ANDA 204535, AMMONIA N-13 Injection USP, 3.75-37.5 mCi/mL

Milex Products, Inc., 5915 Northwest Hwy., Chicago, IL 60631:

- ANDA 072196, MILOPHENE (clomiphene citrate) Tablets, 50 mg

II. Previously Consolidated Application

Sandoz, Inc., 4700 Eon Dr., Wilson, NC 27893, notified the Agency that ANDA 084631, QUINIDINE SULFATE Tablets USP, 200 mg, had previously been consolidated with ANDA 088072. Therefore, FDA rescinds its proposal to withdraw approval of this ANDA.

III. Previously Transferred Application

Pfizer Laboratories, Division of Pfizer, Inc., 235 East 42nd St., New York, NY 10017, notified the Agency that ANDA 060074, PENICILLIN G POTASSIUM for Injection, 20,000,000 units/vial, had previously been transferred to Cultor Food Science, Inc. Therefore, FDA rescinds its proposal to withdraw approval of this ANDA.

IV. Requests to Withdraw Approval

In response to the NOOH, 13 firms notified the Agency that they no longer market 15 of the ANDAs listed in the NOOH and had previously submitted written requests for withdrawal for the following ANDAs:

1. Parkedale Pharmaceuticals, Inc., 501 5th St., Bristol, TN 37620, notified the Agency that they no longer market the product for ANDA 060521, HUMATIN (paromomycin sulfate) Capsules USP, Equivalent to (EQ) 250 mg base. On May 12, 2021 (86 FR 26058), the Agency withdrew approval of this ANDA at the written request of the applicant.

2. Roerig Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017, notified the Agency that they no longer market the product for ANDA 060709, OLEANDOMYCIN Injection. On July 21, 2020 (85 FR 44096), the Agency withdrew approval of this ANDA under the written request of the applicant.
3. Pharmacia and Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49001, notified the Agency that they no longer market the product for ANDA 061034, LINCOMYCIN HYDROCHLORIDE (HCl) Powder. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.
4. Lederle Laboratories, Division of American Cyanamid Co., 401 North Middletown Rd., Pearl River, NY 10965, notified the Agency that they no longer market the product for ANDA 061064, NYSTATIN Ointment. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.
5. Pfizer Laboratories, Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017, notified the Agency that they no longer market the product for ANDA 061087, BENZOCAINE, OXYTETRACYCLINE HCl, and POLYMYXIN B SULFATE OTIC Solution. On July 21, 2020, the Agency withdrew approval of this ANDA under the written request of the applicant.
6. Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950, notified the Agency that they no longer market the product for ANDA 061652, OXYTETRACYCLINE Capsules. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.
7. AH Robins Co., 1211 Sherwood Ave., Richmond, VA 23220, notified the Agency that they no longer market the product for ANDA 061701, TETRACYCLINE Syrup, 125 mg/5 mL. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.

8. Warner Chilcott, Division of Warner Lambert-Pfizer, Inc., 235 East 42nd St., New York, NY 10017, notified the Agency that they no longer market the products for ANDA 061725, TETRACYCLINE HCl Capsules, 250 mg and 500 mg, and ANDA 062175, TETRACYCLINE HCl Capsules, 250 mg. On July 21, 2020, the Agency withdrew approval of these ANDAs under the written request of the applicant.
9. Lederle Laboratories, Division of American Cyanamid Co., 1 Cyanamid Plaza, Wayne, NJ 07470, notified the Agency that they no longer market the products for ANDA 061943, CHLORAMPHENICOL Ophthalmic Solution, 0.5 percent; ANDA 062215, OXYTETRACYCLINE HCl Capsules. On July 21, 2020, the Agency withdrew approval of these ANDAs under the written request of the applicant.
10. Warner-Lambert Co. notified the Agency that they no longer market the product for ANDA 062032, EYPAR (erythromycin stearate) Tablets, EQ 250 mg base and EQ 500 mg base. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.
11. Becton Dickinson and Co., Surgical System, 9450 South State St., Sandy, UT 84070, notified the Agency that they no longer market the product for ANDA 073416, E-Z SCRUB (chlorhexidine gluconate) Topical Sponge, 4 percent. On January 8, 2020 (85 FR 909), the Agency withdrew approval of this ANDA under the written request of the applicant.
12. Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965-1215, notified the Agency that they no longer market the products for ANDA 083001, TRIAMCINOLONE ACETONIDE Aerosol Foam Emulsion. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.
13. Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965-1215, notified the Agency that they no longer market the product for ANDA 084803,

CHLORPROMAZINE HCl Tablets, 10 mg. On May 12, 2021, the Agency withdrew approval of this ANDA under the written request of the applicant.

V. Previously Withdrawn Applications

In the *Federal Register* of September 25, 2020 (85 FR 60474), FDA published a separate notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of ANDAs because the holders of those ANDAs had repeatedly failed to submit the required annual reports and have failed to satisfy the requirement to have an approved risk evaluation and mitigation strategy for the following ANDAs:

1. Everylife, 2021 15th Avenue West, Seattle, WA 98119: ANDA 085217, ACETAMINOPHEN and CODEINE PHOSPHATE Tablet, 325 mg/30 mg
2. Scherer Laboratories, Inc., 2301 Ohio Dr., Suite 234, Plano, TX 75093: ANDA 085638, ACETAMINOPHEN, ASPIRIN, and CODEINE, 150 mg/180 mg/60 mg; ANDA 085639, ACETAMINOPHEN, ASPIRIN, and CODEINE PHOSPHATE Capsule, 150 mg/180 mg/30 mg; ANDA 085640, ACETAMINOPHEN, ASPIRIN, and CODEINE PHOSPHATE Capsule, 150 mg/180 mg/15 mg

The holders of the applications did not respond to the *Federal Register* NOOH of September 25, 2020. Failure to submit a written notice of participation and request for hearing as required by § 314.200 constitutes an election by those holders not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their ANDAs and a waiver of any contentions concerning the legal status of the drug products. On April 9, 2021 (86 FR 18542), the Agency withdrew approval of these ANDAs.

VI. No Response to NOOH Received

The holders of the other 216 applications did not respond to the NOOH. Failure to submit a written notice of participation and request for hearing as required by § 314.200 constitutes an election by those holders not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their ANDAs and a waiver of any contentions

concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the 216 applications listed in table 1.

Table 1.--Approved ANDAS For Which Required Reports Have Not Been Submitted

Application No.	Drug	Applicant
ANDA 020374	Inpersol-LC/LM with Dextrose 1.5% (calcium chloride, dextrose, magnesium chloride, sodium chloride, sodium lactate) Intraperitoneal Solution, 18.4 mg/100 mL; 1.5 grams (g)/100 mL; 5.08 mg/100 mL; 538 mg/100 mL; 448 mg/100 mL Inpersol-LC/LM with Dextrose 2.5% (calcium chloride, dextrose, magnesium chloride, sodium chloride, sodium lactate) Intraperitoneal Solution, 18.4 mg/100 mL; 2.5 g/100 mL; 5.08 mg/100 mL; 538 mg/100 mL; 448 mg/100 mL Inpersol-LC/LM with Dextrose 3.5% (calcium chloride, dextrose, magnesium chloride, sodium chloride, sodium lactate) Intraperitoneal Solution, 18.4 mg/100 mL; 3.5 g/100 mL; 5.08 mg/100 mL; 538 mg/100 mL; 448 mg/100 mL Inpersol-LC/LM with Dextrose 4.25% (calcium chloride, dextrose, magnesium chloride, sodium chloride, sodium lactate) Intraperitoneal Solution, 18.4 mg/100 mL; 4.25 g/100 mL; 5.08 mg/100 mL; 538 mg/100 mL; 448 mg/100 mL	Fresenius USA, Inc., 2637 Shadelands Dr., Walnut Creek, CA 94598
ANDA 040057	Epinephrine and Lidocaine Hydrochloride (HCl) Injection, 0.01 mg/mL; 2% and 0.02 mg/mL; 2%	Eastman Kodak Co., 343 State St., Rochester, NY 14650
ANDA 040168	Hydrocortisone and Acetic Acid Otic Solution USP, 1%/2%	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 West Main St., Morton Grove, IL 60053
ANDA 040192	Prednisolone Syrup, 15 mg/5 mL	WE Pharmaceuticals, Inc., 1142 D St., P.O. Box 1142, Ramona, CA 92065
ANDA 060131	Tetracycline HCl Capsules	Leiner Health Products, Inc., 901 East 233rd St., Carson, CA 90745
ANDA 060461	Neomycin Sulfate Ointment; Neomycin Sulfate and Hydrocortisone Acetate Ointment	Ambix Laboratories, Division of Organics Corp. of America, 210 Orchard St., East Rutherford, NJ 07073
ANDA 060602	Penicillin G Potassium Powder	John D. Copanos and Co., Inc., 6110 Robinwood Rd., Baltimore, MD 21225
ANDA 060627	Tribiotic (polymyxin B sulfate, bacitracin, and neomycin sulfate) Ointment, 5000 units/400 units/5 mg	Ambix Laboratories, Division of Organics Corp. of America

ANDA 060724	Pyocidin-HC (neomycin sulfate, polymyxin B sulfate, and hydrocortisone) Otic Solution	Kasco-EFCO Laboratories, Inc., Cantiague Rock Rd., Hicksville, NY 11802
ANDA 060769	Tetracycline Syrup	West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724
ANDA 060773	Tetracycline Syrup	Leiner Health Products, Inc.
ANDA 060870	Oxytetracycline Injection	Proter S.p.A., c/o Richmar International, Inc., 1706 Birch Rd., McLean, VA 22101
ANDA 061154	Hydrocortisone Acetate and Neomycin Sulfate Ointment	Ambix Laboratories, Division of Organics Corp. of America
ANDA 061209	Bacitracin Ointment USP, 500 units/g	Do.
ANDA 061228	Griseofulvin Capsules	Owen Laboratories, Division of Alcon Laboratories, 3737 Beltline Rd., Dallas, TX 75234
ANDA 061483	Penicillin G Potassium Tablets	Leiner Health Products, Inc.
ANDA 061518	Bacitracin Zinc Ointment	Rexall Drug Co., 135 Chesterfield Industrial Blvd., Chesterfield, MO 63017
ANDA 061519	Bacitracin Zinc and Neomycin Sulfate Ointment	Do.
ANDA 061520	Bacitracin Zinc and Neomycin Sulfate/Polymyxin B Sulfate Ointment	Do.
ANDA 061521	Bacitracin Zinc, Benzocaine, and Neomycin Sulfate/Polymyxin B Sulfate Ointment	Do.
ANDA 061528	Penicillin V Potassium Tablets USP, EQ 250 mg base and EQ 500 mg base	American Antibiotics, Inc., 6110 Robinwood Rd., Baltimore, MD 21225
ANDA 061529	Penicillin V Potassium for Oral Solution USP, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Do.
ANDA 061532	Ampicillin Trihydrate Capsules	Leiner Health Products, Inc.
ANDA 061601	Ampicillin for Oral Suspension USP, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	American Antibiotics, Inc.
ANDA 061602	Ampicillin Capsules USP, EQ 250 mg base and EQ 500 mg base	Do.
ANDA 061632	Ampicillin Trihydrate Capsules, 250 mg	Chromalloy Pharmaceuticals, Inc., 5353 Grosvenor Blvd., Los Angeles, CA 90066
ANDA 061674	Penicillin V Potassium Tablets	Leiner Health Products, Inc.
ANDA 061697	Griseofulvin Capsules	Watson Laboratories, Inc., 311 Bonnie Cir., Corona, CA 92880
ANDA 061699	Bacitracin Powder for Rx Compounding, 5,000,000 units/bottle	Apothekernes Laboratorium A.S., c/o AL Laboratories, Inc., 1 Executive Dr., Fort Lee, NJ 07024
ANDA 061833	Oxytetracycline HCl Capsules, 250 mg	Pliva, c/o Transtrade USA, Ltd., 515 Madison Ave., 4th Floor East, New York, NY 10022
ANDA 061847	Bleomycin Sulfate Injection	Takasaki Plant, Nippon Kayaku Co., Ltd., 500 5th Ave., Suite 1726, New York, NY 10110

ANDA 061857	Penicillamine Powder	Chemiewerk Homberg, c/o Wallace Laboratories, Cranbury, NJ 08512
ANDA 061903	Bacitracin Zinc and Polymyxin B Sulfate Ointment	Ambix Laboratories, Division of Organics Corp. of America
ANDA 062085	Tetracycline HCl Capsules, 250 mg	MM Mast and Co., 4152 Ruple Rd., Cleveland, OH 44121
ANDA 062205	Cefaclor Capsules USP, EQ 250 mg base and EQ 500 mg base	Ceph International Corp. c/o Mova Pharmaceutical Corp., State Rd. #1, Jose Garrido St., Cagus, PR 00725
ANDA 062340	Gentamicin Sulfate Injection	Pharmaceutical Specialist Association, 9852 Cowden St., Philadelphia, PA 19115
ANDA 062467	E-Solve 2 (erythromycin) Lotion, 2%	Syosset Laboratories, Inc., 150 Eileen Way, Syosset, NY 11791
ANDA 062758	Eryzole (erythromycin ethylsuccinate and sulfisoxazole acetyl) Granules, EQ 200 mg base/5 mL; EQ 600 mg base/5 mL	Alra Laboratories, Inc., 3850 Clearview Ct., Gurnee, IL 60031
ANDA 062944	Clindamycin Phosphate Topical Solution USP, EQ 1% base	BOCA Pharmacal, LLC., 3550 North West 126th Ave., Coral Springs, FL 33065
ANDA 070104	Chlorhexidine Gluconate Topical Solution, 4%	Matrix Medical Corp., 1825 South 3730 West, Salt Lake City, UT 84104
ANDA 071054	Constilac (lactulose) Solution, 10 g/15 mL	Alra Laboratories, Inc.
ANDA 071057	Ibu-tab 200 (ibuprofen) Tablets, 200 mg	Do.
ANDA 071058	Ibu-tab (ibuprofen) Tablets, 400 mg	Do.
ANDA 071059	Ibu-tab (ibuprofen) Tablets, 600 mg	Do.
ANDA 071104	Leucovorin Calcium Tablets, EQ 15 mg base	Xanodyne Pharmacal, Inc., 7310 Turfway Rd., Suite 490, Florence, KY 41042
ANDA 071139	Trazodone HCl Tablets, 50 mg	American Therapeutics, Inc., 89 Carlough Rd., Bohemia, NY 11716
ANDA 071140	Trazodone HCl Tablets, 100 mg	Do.
ANDA 071331	Cholac (lactulose) Solution, 10 g/15 mL	Alra Laboratories, Inc.
ANDA 071362	Meclofenamate Sodium Capsules USP, 50 mg	American Therapeutics, Inc.
ANDA 071363	Meclofenamate Sodium Capsules USP, 100 mg	Do.
ANDA 071419	Brian Care (chlorhexidine gluconate) Topical Solution, 4%	Soapco, Inc., P.O. Box 5490, Pleasanton, CA 94566
ANDA 071429	Clorazepate Dipotassium Capsules, 3.75 mg	American Therapeutics, Inc.
ANDA 071430	Clorazepate Dipotassium Capsules, 7.5 mg	Do.
ANDA 071431	Clorazepate Dipotassium Capsules, 15 mg	Do.
ANDA 071569	Danazol Capsules USP, 200 mg	Do.
ANDA 071787	Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg	Alra Laboratories, Inc.
ANDA 071788	Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg	Do.
ANDA 071789	Gen-Xene (clorazepate dipotassium) Tablets, 15 mg	Do.
ANDA 071955	Oxazepam Capsules USP, 10 mg	American Therapeutics, Inc.
ANDA 071956	Oxazepam Capsules USP, 15 mg	Do.

ANDA 071957	Oxazepam Capsules USP, 30 mg	Do.
ANDA 071962	Leucovorin Calcium Tablets, EQ 10 mg base	Xanodyne Pharmacal, Inc.
ANDA 071965	Ibu-tab (ibuprofen) Tablets, 800 mg	Alra Laboratories, Inc.
ANDA 072022	Triamterene and Hydrochlorothiazide Tablets, 75 mg/50 mg	American Therapeutics, Inc.
ANDA 072129	Maprotiline HCl Tablets USP, 25 mg	Do.
ANDA 072130	Maprotiline HCl Tablets USP, 50 mg	Do.
ANDA 072131	Maprotiline HCl Tablets USP, 75 mg	Do.
ANDA 072190	Metaproterenol Sulfate Inhalation Solution, 5%	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 072255	Microderm (chlorhexidine gluconate) Topical Solution, 4%	Johnson and Johnson Medical, Inc., 2500 Arbrook Blvd., Arlington, TX 76014
ANDA 072292	Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%	Do.
ANDA 072295	Microderm (chlorhexidine gluconate) Topical Sponge, 4%	Do.
ANDA 072307	Fenoprofen Calcium Capsules USP, 200 mg	American Therapeutics, Inc.
ANDA 072308	Fenoprofen Calcium Capsules USP, 300 mg	Do.
ANDA 072309	Fenoprofen Calcium Tablets USP, 600 mg	Do.
ANDA 072782	Prazosin HCl Capsules USP, 1 mg	Do.
ANDA 072783	Prazosin HCl Capsules USP, 2 mg	Do.
ANDA 072784	Prazosin HCl Capsules USP, 5 mg	Do.
ANDA 073535	Piroxicam Capsules, 10 mg	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124
ANDA 074523	Metromidol (metronidazole) Tablets, 250 mg and 500 mg	Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/o Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162
ANDA 074560	Flurbiprofen Tablets USP, 100 mg	Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520
ANDA 074702	Metaproterenol Sulfate Syrup, 10 mg/5 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 074881	Iopamidol Injection, 41%, 51%, 61%, and 76%	Cook Imaging Corp., 927 South Curry Pike, P.O. Box 3068, Bloomington, IN 47403
ANDA 075181	Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg base/5 mL	WE Pharmaceuticals, Inc.
ANDA 075260	Tretinoin Topical Solution, 0.05%	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 075414	Nifedipine Extended-Release Tablets, 90 mg	Martec USA, LLC, 1800 North Topping Ave., Kansas City, MO 64120
ANDA 075507	Ipratropium Bromide Inhalation Solution, 0.02%	Pharmascience, Inc., 10 Orchard Pl., Tenafly City, NJ 07670

ANDA 075569	Thallous Chloride TL 201 Injection USP, 1 mCi/mL	Trace Life Sciences, Inc., 2101 Shady Oaks, Denton, TX 76205
ANDA 075586	Metaproterenol Sulfate Inhalation Solution, 0.4% and 0.6%	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 075619	Minoxidil Extra Strength (for Men) Topical Solution, 5%	Avacor Products, LLC, 227 East 56th St., 3rd Floor, New York, NY 10022
ANDA 075766	Calcitriol Injection, 1 microgram (mcg)/mL and 2 mcg/mL	Fresenius Medical Care North America, 95 Hayden Ave., Lexington, MA 02421
ANDA 075941	Strontium Chloride SR-89 Injection, 1 mCi/mL	Bio-Nucleonics, Inc., 1600 Market St., Suite 13200, Philadelphia, PA 19103
ANDA 077072	Ipratropium Bromide Inhalation Solution, 0.02%	Landela Pharmaceutical, 776 East Riverside Dr., Suite 150, Eagle, ID 83616
ANDA 077218	ThyroShield (potassium iodide) Oral Solution USP, 65 mg/mL	Arco Pharmaceuticals, LLC, 7605 Maryland Ave., St. Louis, MO 63105
ANDA 077569	Albuterol Sulfate Inhalation Solution, EQ 0.083% base	Landela Pharmaceutical
ANDA 080024	Sulfacel-15 (sulfacetamide sodium) Ophthalmic Solution, 15%	Optopics Laboratories Corp., P.O. Box 210, Fairton, NJ 08320
ANDA 080036	Sosol (sulfisoxazole) Tablets, 500 mg	MK Laboratories, Inc., 424 Grasmere Ave., Fairfield, CT 06430
ANDA 080366	Soxazole (sulfisoxazole) Tablets, 500 mg	Alra Laboratories, Inc.
ANDA 080380	Bamate (meprobamate) Tablets, 200 mg and 400 mg	Do.
ANDA 080483	Hi-cor (hydrocortisone) Cream, 2.5%	C and M Pharmacal, Inc., 1519 East 8 Mile Rd., Hazel Park, MI 48030
ANDA 080492	Reserpine Tablets, 0.1 mg and 0.25 mg	Marshall Pharmacal Corp., 89 Michael St., South Hackensack, NJ 07606
ANDA 080518	Dimenhydrinate Tablets, 50 mg	Alra Laboratories, Inc.
ANDA 080519	Diphenhydramine HCl Capsules, 25 mg and 50 mg	Do.
ANDA 080525	Reserpine Tablets, 0.1 mg and 0.25 mg	MK Laboratories, Inc.
ANDA 080592	Diphenhydramine HCl Capsules, 50 mg	Valeant Pharmaceuticals International, One Enterprise, Aliso Viejo, CA 92656
ANDA 080660	Ocusulf (sulfacetamide sodium) Ophthalmic Solution, 10% and 30%	Miza Pharmaceuticals USA, Inc., c/o Optopics Laboratories, 40 Main St., P.O. Box 210, Fairton, NJ 08320
ANDA 080714	Diphenhydramine HCl Oral Solution, 12.5 mg/5 mL	Alra Laboratories, Inc.
ANDA 080715	Dimenhydrinate Oral Solution, 12.5 mg/4 mL	Do.
ANDA 080941	Isoniazid Tablets, 100 mg	MK Laboratories, Inc.
ANDA 080970	Methscopolamine Bromide Tablets, 2.5 mg	Private Formulations, Inc., 460 Plainfield Ave., Edison, NJ 08818
ANDA 083087	Diphenhydramine HCl Capsules, 25 mg and 50 mg	MK Laboratories, Inc.

ANDA 083088	Diphenhydramine HCl Elixir, 12.5 mg/5 mL	Do.
ANDA 083264	Pentobarbital Sodium Capsules, 100 mg	Valeant Pharmaceuticals International
ANDA 083286	Chlorpheniramine Maleate Tablets	Marshall Pharmacal Corp.
ANDA 083315	Procaine HCl Injection, 1% and 2%	Elkins Sinn Pharmaceutical Co., c/o ESI Lederle, 2 Esterbrook Ln., Cherry Hill, NJ 08003
ANDA 083320	Acetazolamide Tablets, 250 mg	Alra Laboratories, Inc.
ANDA 083389	Epinephrine and Lidocaine HCl Injection, 0.01 mg/mL and 1%	Dell Laboratories, Inc., 668 Front St., Teaneck, NJ 07666
ANDA 083390	Epinephrine and Lidocaine HCl Injection, 0.01 mg/mL and 2%	Do.
ANDA 083457	Vitamin A Palmitate Capsules, EQ 25,000 units base and EQ 50,000 units base	MK Laboratories, Inc.
ANDA 083524	Butabarbital Sodium Tablets, 16.2 mg	Marshall Pharmacal Corp.
ANDA 083525	Niacin Tablets, 500 mg	MK Laboratories, Inc.
ANDA 083526	Folic Acid Tablets, 1 mg	Do.
ANDA 083658	Promethazine HCl Tablets, 25 mg	Private Formulations, Inc.
ANDA 083806	Dexamethasone Tablets, 0.75 mg	Phoenix Laboratories, Inc., 175 Lauman Ln., East Hicksville, NY 11801
ANDA 083827	Pramine (imipramine HCl) Tablets, 10 mg, 25 mg, and 50 mg	Alra Laboratories, Inc.
ANDA 083858	Butabarbital Sodium Tablets, 32.4 mg	Marshall Pharmacal Corp.
ANDA 083863	Sulfisoxazole Cream	Holland Rantos Co., Inc., P.O. Box 385, Piscataway, NJ 08854
ANDA 084185	Bethanechol Chloride Tablets, 10 mg	Wendt Laboratories, Inc., 200 West Beaver, P.O. Box 128, Belle Plaine, MN 56011
ANDA 084186	Bethanechol Chloride Tablets, 25 mg	Do.
ANDA 084188	Myotonachol (bethanechol chloride) Tablets, 5 mg, 10 mg, and 25 mg	Glenwood, Inc., 83 North Summit St., P.O. Box 518, Tenafly, NJ 07670
ANDA 084246	Cortisone Acetate Tablets, 25 mg	Everylife, 2021 15th Ave., West Seattle, WA 98119
ANDA 084439	Prednisolone Tablets, 1 mg, 2.5 mg, and 5 mg	Do.
ANDA 084440	Prednisone Tablets, 1 mg, 2.5 mg, and 5 mg	Do.
ANDA 084494	Hydrochlorothiazide Tablets	West-Ward Pharmaceutical Corp.
ANDA 084590	Pentobarbital Sodium Capsules, 100 mg	Anabolic, Inc., 1835 East Cheyenne Rd., Colorado Springs, CO 80905
ANDA 084687	Niacin Tablets, 500 mg	Zzeon Pharmaceuticals, Ltd., Jamboree at Kevin, Irvine, CA 92705
ANDA 084714	Hydro-Reserp (hydrochlorothiazide and reserpine) Tablets, 50 mg/0.125 mg	ABC Holding Corp., P.O. Box 307, 70945 Van Dyke Ave., Romeo, MI 48065
ANDA 084729	Lidocaton (epinephrine and lidocaine HCl) Injection, 0.01 mg/mL and 2%	Pharmaton, Ltd., c/o Bass Ullmna and Lustigman, 747 3rd Ave., New York, NY 10017
ANDA 084872	Meclizine HCl Tablets, 25 mg	CM Bundy Co., 2055 Reading Rd., Cincinnati, OH 45205

ANDA 084902	Promethacon (promethazine HCl) Suppository, 50 mg	Polymedica Industries, Inc., 2 Constitution Way, Woburn, MA 01801
ANDA 084931	Methamphetamine HCl Tablets, 5 mg and 10 mg	Rexar Pharmacal, 396 Rockaway Ave., Valley Stream, NY 11581
ANDA 084933	Diethylstilbestrol Tablets, 1 mg	West-Ward Pharmaceutical Corp.
ANDA 084977	Halothane Inhalation, 99.99%	BH Chemicals, Inc., 500 5th Ave., New York, NY 10036
ANDA 085009	Lygen (chlordiazepoxide HCl) Capsules, 10 mg	Alra Laboratories, Inc.
ANDA 085039	Folic Acid Tablets USP, 1 mg	Wendt Laboratories, Inc.
ANDA 085040	Isoniazid Tablets USP, 100 mg	Do.
ANDA 085041	Meclizine HCl Tablets, 25 mg	Do.
ANDA 085042	Methocarbamol Tablets USP, 500 mg	Do.
ANDA 085044	Reserpine Tablets USP, 0.25 mg	Do.
ANDA 085075	Aerolate III (theophylline) Extended-Release Capsules, 65 mg Aerolate JR (theophylline) Extended-Release Capsules, 130 mg Aerolate SR (theophylline) Extended-Release Capsules, 260 mg	Fleming and Co. Pharmaceuticals, Inc., 1600 Fenton Park Dr., Fenton, MO 63026
ANDA 085107	Lygen (chlordiazepoxide HCl) Capsules, 5 mg	Alra Laboratories, Inc.
ANDA 085108	Lygen (chlordiazepoxide HCl) Capsules, 25 mg	Do.
ANDA 085125	Methyltestosterone Sublingual Tablets, 10 mg	Tablicaps, Inc., P.O. Box 5555, Franklinville, NJ 08322
ANDA 085235	Chlordiazepoxide HCl Capsules	Abbott Laboratories, Pharmaceutical Products Division, 100 Abbott Park Rd., Abbott Park, IL 60064
ANDA 085236	Chlordiazepoxide HCl Capsules	Do.
ANDA 085252	Meclizine HCl Tablets, 25 mg	ABC Holding Corp.
ANDA 085253	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 085282	Hydrocortisone Lotion, 0.5% and 1%	Mericon Industries, Inc., 8819 North Pioneer Rd., Peoria, IL 61615
ANDA 085383	Butabarbital Sodium Elixir, 30 mg/5 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 085411	Phentermine HCl Capsules, 30 mg	ABC Holding Corp.
ANDA 085511	Cam-Metrazine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 085512	Phenazine-35 (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 085550	Butabarbital Sodium Tablets, 30 mg	CM Bundy Co.
ANDA 085569	Chlorothiazide Tablets, 250 mg	ABC Holding Corp.
ANDA 085587	Meclizine HCl Chewable Tablets	Camall Co., Inc., 60950 Van Dyke Ave., P.O. Box 218, Washington, MI 48094
ANDA 085672	Hydrochlorothiazide Tablets, 50 mg	ABC Holding Corp.
ANDA 085756	Cam-Metrazine (phendimetrazine tartrate) Tablets, 35 mg	Camall Co., Inc.
ANDA 085766	Atropine Sulfate and Diphenoxylate HCl Tablets, 0.025 mg/2.5 mg	Private Formulations, Inc.
ANDA 085888	Brompheniramine Maleate Tablets	Leiner Health Products, Inc.

ANDA 085891	Meclizine HCl Tablets, 25 mg	Anabolic, Inc.
ANDA 085895	Secobarbital Sodium Capsules, 100 mg	Everylife
ANDA 086008	Hydrocortisone and Urea Cream, 1%/10%	Bioglan Laboratories, Ltd., 450 Hilltop Rd., Riegelsville, PA 18077
ANDA 086077	Nitrofurazone Ointment, 0.2%	Ambix Laboratories, Division of Organics Corp. of America
ANDA 086079	Hydrocortisone Ointment, 1%	Do.
ANDA 086080	Hydrocortisone Cream, 1%	Do.
ANDA 086141	Tolbutamide Tablets, 500 mg	Alra Laboratories, Inc.
ANDA 086260	Ona-Mast (phentermine HCl) Tablets, 8 mg	MM Mast and Co.
ANDA 086271	Hydrocortisone Cream, 2.5%	Ambix Laboratories, Division of Organics Corp. of America
ANDA 086272	Hydrocortisone Ointment, 2.5%	Do.
ANDA 086498	Amitriptyline HCl Tablets, 10 mg	Alra Laboratories, Inc.
ANDA 086499	Amitriptyline HCl Tablets, 50 mg	Do.
ANDA 086500	Amitriptyline HCl Tablets, 150 mg	Do.
ANDA 086501	Amitriptyline HCl Tablets, 100 mg	Do.
ANDA 086502	Amitriptyline HCl Tablets, 25 mg	Do.
ANDA 086503	Amitriptyline HCl Tablets, 75 mg	Do.
ANDA 086511	Ona-Mast (phentermine HCl) Capsules, 30 mg	MM Mast and Co.
ANDA 086516	Ona-Mast (phentermine HCl) Capsules, 30 mg	Do.
ANDA 086550	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Shire Richwood, Inc., 7900 Tanners Gate Dr., Suite 200, Florence, KY 41042
ANDA 086551	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086552	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086553	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086554	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086735	Phentermine HCl Capsules, 15 mg	Camall Co., Inc.
ANDA 086748	Theophylline Elixir, 80 mg/15 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 086766	Nitrofurazone Ointment, 0.2%	Wendt Laboratories, Inc.
ANDA 087081	Nitrofurazone Topical Solution, 0.2%	Do.
ANDA 087226	Phentermine HCl Capsules, 30 mg	Camall Co., Inc.
ANDA 087371	X-Trozine L.A. (phendimetrazine tartrate) Extended-Release Capsules, 105 mg	Shire Richwood, Inc.
ANDA 087392	Aminophylline Injection, 25 mg/mL	Pharma Serve, Inc., Subsidiary of Torigian Laboratories, 218-20 98th Ave., Queens Village, NY 11429
ANDA 087394	X-Trozine (phendimetrazine tartrate) Capsules, 35 mg	Shire Richwood, Inc.
ANDA 087442	Neosar (cyclophosphamide) for Injection, 100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial, and 2 g/vial	Bedford Laboratories, Division of Ben Venue Laboratories, Inc., 300 Northfield Rd., Bedford, OH 44146

ANDA 087487	Melfiat-105 (phendimetrazine tartrate) Extended-Release Capsules, 105 mg	Numark Laboratories, Inc., 75 Mayfield Ave., Edison, NJ 08837
ANDA 087636	Tropicamide Ophthalmic Solution, 0.5%	Miza Pharmaceuticals USA, Inc., c/o Optopics Laboratories
ANDA 087637	Tropicamide Ophthalmic Solution, 1%	Do.
ANDA 087681	Paracaine (proparacaine HCl) Ophthalmic Solution, 0.5%	Optopics Laboratories Corp.
ANDA 087764	Oby-Trim (phentermine HCl) Capsules, 30 mg	Shire Richwood, Inc.
ANDA 087932	Triamcinolone Acetonide Cream, 0.025%	Ambix Laboratories, Division of Organics Corp. of America
ANDA 088786	Sodium Polystyrene Sulfonate USP Powder, 453.6 g/bottle	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 088897	Promethazine VC Plain (phenylephrine HCl and promethazine HCl) Syrup, 5 mg/5 mL and 6.25 mg/5 mL	Do.
ANDA 089141	Aerolate (theophylline) Oral Solution, 150 mg/15 mL	Fleming and Co. Pharmaceuticals, Inc.
ANDA 089417	Methocarbamol Tablets USP, 500 mg	American Therapeutics, Inc.
ANDA 089418	Methocarbamol Tablets USP, 750 mg	Do.
ANDA 089478	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg	Do.
ANDA 089479	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Do.
ANDA 089480	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg	Do.
ANDA 089514	Trihexyphenidyl HCl Elixir, 2 mg/5 mL	Pharmaceutical Ventures, Ltd., P.O. Box D3700, Pomona, NY 10970
ANDA 089726	Prednisone Oral Solution, 5 mg/5 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.

FDA finds that the holders of the ANDAs listed in table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the ANDAs listed in table 1 and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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