Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 022510	ABSTRAL	Fentanyl Citrate	EQ 0.1 mg base; EQ 0.2 mg base; EQ 0.3 mg base; EQ 0.4 mg base; EQ 0.6 mg base; EQ 0.8 mg base.	Tablet; Sublingual	Sentynl Therapeutics, Inc.
NDA 050011	PATHOCIL	Dicloxacillin Sodium	EQ 250 mg base; EQ 500 mg base.	Capsule; Oral	Wyeth-Ayerst Labs.
NDA 204308	EPANED KIT	Enalapril Maleate	1 mg/mL	For Solution; Oral	Silvergate Pharms., Inc.
NDA 207233	VIVLODEX	Meloxicam	5 mg; 10 mg	Capsule; Oral	Zyla.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the "Discontinued Drug Product List" section of the Orange Book. The Discontinued Drug Product List identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 19, 2021.

Lauren K. Roth,

 $Associate\ Commissioner\ for\ Policy.$ [FR Doc. 2021–23084 Filed 10–21–21; 8:45 am]

BILLING CODE 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DATES: Approval is withdrawn as of November 22, 2021.

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"). 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, DUVOIĎ (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, ASPĬRIN AND METHOCARBAMOL Tablets, 325 mg/ 400 mg

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.

¹85 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.

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
- 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	Fresenius USA, Inc., 2637 Shadelands Dr., Walnut Creek, CA 94598.
	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.	
ANDA 040057	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		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	cortisone 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 ANDA 060870	Tetracycline Syrup Oxytetracycline Injection	Leiner Health Products, Inc. Proter S.p.A., c/o Richmar International, Inc., 1706 Birch
ANDA 061154 ANDA 061209 ANDA 061228	Bacitracin Ointment USP, 500 units/g	Rd., McLean, VA 22101. Ambix Laboratories, Division of Organics Corp. of America. Do. Owen Laboratories, Division of Alcon Laboratories, 3737
ANDA 061483 ANDA 061518		Beltline Rd., Dallas, TX 75234. Leiner Health Products, Inc. Rexall Drug Co., 135 Chesterfield Industrial Blvd., Chesterfield, MO 63017.
ANDA 061519 ANDA 061520	Bacitracin Zinc and Neomycin Sulfate OintmentBacitracin Zinc and Neomycin Sulfate/Polymyxin B Sulfate	Do. Do.
ANDA 061521	Ointment. 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 ANDA 061601	Ampicillin Trihydrate Capsules	Leiner Health Products, Inc. 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 ANDA 061697	Penicillin V Potassium Tablets	Leiner Health Products, Inc. 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.

TABLE 1—APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED—Continued

ANDA 061903 Bacitracin Zinc and Polymyxin B Sulfate Ointment ANDA 062085 Tetracycline Hot Capsules, 250 mg ANDA 062085 Tetracycline Hot Capsules, 250 mg ANDA 062085 Tetracycline Hot Capsules, 250 mg ANDA 062340 Gentamicin Sulfate Injection ANDA 062340 E-Solve 2 (erythromycin) Lotion, 2% ANDA 062467 E-Solve 2 (erythromycin) Lotion, 2% ANDA 062468 Tetracycline Hot Capsules USP, 250 mg ANDA 070104 Childramycin Phosphate Topical Solution USP, EQ 1% base ANDA 070104 Childramycin Phosphate Topical Solution USP, EQ 1% base ANDA 070105 ANDA 070107 Corresponding Capsules USP, 250 mg ANDA 070108 ANDA 070109 ANDA 070109 Trazodone HCI Tablets, 500 mg ANDA 070109 ANDA 0701139 Trazodone HCI Tablets, 500 mg ANDA 0701139 Trazodone HCI Tablets, 500 mg ANDA 0701139 Trazodone HCI Tablets, 500 mg ANDA 0701149 Brian Care (childrawsinie gluconate) Topical Solution, 4% ANDA 070140 Childramycin Phosphate Topical Solution USP, EQ 11% ANDA 0701139 Trazodone HCI Tablets, 500 mg ANDA 0701139 Trazodone HCI Tablets, 500 mg ANDA 0701139 Trazodone HCI Tablets, 500 mg ANDA 0701139 Trazodone HCI Tablets, 100 mg ANDA 0701149 Brian Care (childrawsinie gluconate) Topical Solution, 4% ANDA 0701149 Brian Care (childrawsinie gluconate) Topical Solution, 4% ANDA 0701149 Brian Care (childrawsinie gluconate) Topical Solution, 4% ANDA 0701149 Brian Care (childrawsinie gluconate) Topical Solution, 4% ANDA 0701149 Brian Care (childrawsinie gluconate) Topical Solution, 5% ANDA 070129 ANDA 070129 Melaproterenol Sulfate Inhalation Solution, 5% ANDA 070129 Melaproterenol Sulfate Inhalation Solution, 6% ANDA 0701295 Melaprotenenol Sulfate Inhalation	Application No.	Drug	Applicant
ANDA 061903 Balciracin Zinc and Polymykin B Sulfate Orinfment	ANDA 061857	Penicillamine Powder	Chemiewerk Homberg, c/o Wallace Laboratories, Cranbury,
ANDA 062085 — Terracycline HCI Capsules, 250 mg — MM Mast and Co., 4152 Ruple Rd, Cleveland, CH 4172 Details Cedarion Capsules USP, 20 250 mg base and EO 500 mg base. ANDA 062340 — E-Solve 2 (erythromycin) Lolion, 2% — Stafe Rd, 41, Jose Gardid SN, Cagus, PR 00725 ANDA 062467 — E-Solve 2 (erythromycin) Lolion, 2% — Stafe Rd, 41, Jose Gardid SN, Cagus, PR 00725 — Proceeding Control of the Cont	ANDA 061903	Bacitracin Zinc and Polymyxin B Sulfate Ointment	
ANDA 062467 Gentamicin Sulfate Injection Pharmacoulical Specialist Associationes, Inc., 150 Elieen Way, Syosset, NY Philadelphia, PA 19115. ANDA 062467 E-Solve 2 (erythromycin) Lotion, 2% Philadelphia, PA 19115. ANDA 062758 Eprote (erythromycin ethylsuccinate and sulfisoxxazole acety) Granulas, EQ 200 mg base/5 mL, EQ 600 mg base/5 mL, EQ 60	ANDA 062085		MM Mast and Co., 4152 Ruple Rd., Cleveland, OH 44121.
ANDA 082340 — Gentamicin Sulfate Injection — Pharmacoutical Specialist Association, 982 Cowden St., Philadolphia, pp. 19115. Syssest Laboratories, Inc., 150 Eileen Way, Syssest, NY 17971. ANDA 082758 — Espoke (erythromycin ethylsuccinate and sulfisoxazzole according to the property of	ANDA 062205	, ,	
ANDA 062467 E-Solve 2 (erythromycin) Lotion, 2% Syssest Laboratories, Inc., 150 Elieen Way, Syossel, NY 11791. ANDA 062758 Eryzole (erythromycin ethylsuccinate and sulfisoxazole acely) Granuluse, EG 200 mg basel 5 mt. EQ 000 mg basel 5 mt. E	AND A 000040		
ANDA 0624578	ANDA 062340	Gentamicin Suitate injection	· · · · · · · · · · · · · · · · · · ·
ANDA 062758	ANDA 062467	E-Solve 2 (erythromycin) Lotion, 2%	
fiyl Granules, EÖ 200 mg base/5 mt. EØ 600 mg base/5 mt. EØ 600 mg base/5 mt. EØ 60031.		, , , , , , , , , , , , , , , , , , ,	
ANDA 07104 — Chlorhexidine Gluconate Topical Solution USP, EQ 1% base BCCA Pharmacal, LLC, 3550 North West 126th Ave. Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1826 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1826 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1825 South 3730 West, Salt Lake Carl Springs, El 33066. Matrix Medical Corp. 1826 South Springs, El 23067. Do. And Carl Springs, El 33066. Matrix Medical Corp. 1826 South Springs, El 23067. Do. And Carl Springs, El 33067. Do. An	ANDA 062758	tyl) Granules, EQ 200 mg base/5 mL; EQ 600 mg base/5	
ANDA 071054 Chlorhexidine Gluconate Topical Solution, 4% Matrix Medical Corp., 1825 South 3730 West, Salt Lake City, UT 8104. ANDA 071057 Ibu-tab 200 (ibuprofen) Tablets, 200 mg Do.	ANDA 062944		
ANDA 071055 Ilbu-tab 200 (buprofen) Tablets, 200 mg		•	Matrix Medical Corp., 1825 South 3730 West, Salt Lake City, UT 84104.
ANDA 071056 Ibu-tab (buprofen) Tablets, 400 mg ANDA 071059 Ibu-tab (buprofen) Tablets, 600 mg 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 ANDA 071311 Cholac (lactulose) Solution, 10 g/15 ml.			
ANDA 071059 Ibu-tab (buprofen) Tablets, 600 mg Do. ANDA 071104 Leucovorin Calcium Tablets, EQ 15 mg base Storens Sto			
ANDA 071149 Leucovorin Calcium Tablets, EO 15 mg base			
ANDA 071139 Trazodone HCI Tablets, 50 mg ANDA 071310 Trazodone HCI Tablets, 50 mg ANDA 071311 Trazodone HCI Tablets, 100 mg ANDA 071311 ANDA 071362 Moclofenamate Sodium Capsules USP, 50 mg ANDA 071369 Meclofenamate Sodium Capsules USP, 50 mg ANDA 071419 Brian Care (holthorexidine gluconate) Topical Solution, 4% ANDA 071419 Brian Care (holthorexidine gluconate) Topical Solution, 4% ANDA 071419 Brian Care (holthorexidine gluconate) Topical Solution, 4% ANDA 071430 Clorazepate Dipotassium Capsules USP, 70 mg ANDA 071430 Clorazepate Dipotassium Capsules SP, 75 mg ANDA 071786 Danazol Capsules USP, 200 mg ANDA 071787 Gen-Xene (dorazepate dipotassium) Tablets, 3.75 mg ANDA 071788 Gen-Xene (dorazepate dipotassium) Tablets, 5.75 mg ANDA 071788 Gen-Xene (dorazepate dipotassium) Tablets, 5.75 mg ANDA 071955 Oxazepam Capsules USP, 10 mg ANDA 071955 Oxazepam Capsules USP, 10 mg ANDA 071956 Ibu-tab (huprofen) Tablets, 80 mg ANDA 071965 Ibu-tab (huprofen) Tablets, 80 mg ANDA 072131 Maprotiline HCI Tablets USP, 50 mg ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 4% ANDA 072307 Fenoprofen Calcium Capsules USP, 900 mg ANDA 072307 Fenoprofen Calcium Capsules USP, 900 mg ANDA 072307 Fenoprofen Calcium Capsules USP, 900 mg ANDA 072783 Prazosin HCI Capsules USP, 50 mg ANDA 072784 Prazosin HCI Capsules USP, 50 mg ANDA 072783 Prazosin HCI Capsules USP, 50 mg ANDA 072783 Prazosin HCI Capsules USP, 50 mg ANDA 072783 Prazosin HCI Capsules USP, 50 mg ANDA 072784 Prazosin HCI Capsules USP, 50 mg ANDA 072785 Prazosin HCI Capsules USP, 50 mg ANDA 072784 Prazosin HCI Capsules USP, 50 mg ANDA 072785 Prazosin HCI Capsules USP, 50 mg ANDA 072784 Prazosin HCI Caps			
ANDA 071140 Trazodone HCI Tablets, 100 mg Do Cholac (lactulose) Solution, 10 g/15 mL Do Cholac (lactulose) Solution, 20 g/15 mL Do Cholac (lactulose) Solu		. •	Florence, KY 41042.
ANDA 071140 ANDA 0713131 ANDA 071362 ANDA 071362 ANDA 071363 ANDA 071449 Clorazepata Dipotassium Capsules, 3.75 mg ANDA 071364 ANDA 071449 Clorazepata Dipotassium Capsules, 15 mg ANDA 071440 ANDA 071440 ANDA 071451 Clorazepata Dipotassium Capsules, 15 mg ANDA 071440 ANDA 071463 ANDA 0714767 ANDA 071787 Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg ANDA 071788 ANDA 071789 ANDA 071895 ANDA 071896 ANDA 071896 ANDA 071896 ANDA 071896 ANDA 071897 ANDA 071897 ANDA 071896 ANDA 071897 ANDA 071897 ANDA 071897 ANDA 071898 ANDA 07189	ANDA 071139	Trazodone HCl Tablets, 50 mg	
ANDA 071382 Meclofenamate Sodium Capsules USP, 50 mg ANDA 071363 Meclofenamate Sodium Capsules USP, 50 mg ANDA 071419 Brian Care (chlorhoxidine gluconate) Topical Solution, 4%-60 Metaproternol Sulfate Inhalation Solution, 4%-60 Metaproternol Sulfate Susp. 25 mg ANDA 072308 Fenoprofen Calcium Tablets USP, 200 mg ANDA 072782 Prazosin HCl Capsules USP, 200 mg ANDA 072783 Prazosin HCl Capsules USP, 200 mg ANDA 072784 Metaproternol Sulfate Syrup, 10 mg ANDA 074702 Metaproternol Sulfate Syrup, 10 mg ANDA 07402 Metaproternol Sulfate Syrup, 10 mg ANDA 07402 Metaproternol Sulfate Syrup, 10 mg ANDA 074702 Metaproternol Sulfate Syrup, 10 mg/5 m. ANDA 07402 Metaproternol Sulfate Syrup, 10 mg ANDA 074702 Metaproternol Sulfate Syrup, 10 mg/5 m. ANDA 07402 Metaproternol Sulfate Syrup, 10 mg/5 m. ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, 60 mg m. ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, 61 mg m. Arra Laboratories, Inc. Arra Laboratories, Inc. Arra Laboratories, Inc. Do. Do. Armerican Therapeutics, Inc. Do. Armer	ANDA 071140	Trazodone HCI Tablete 100 mg	
ANDA 071362 ANDA 071363 AMCIO (choramate Sodium Capsules USP, 10 mg ANDA 071363 AMCIO (choramate Sodium Capsules USP, 10 mg ANDA 071439 Clorazepate Dipotassium Capsules, 3.75 mg ANDA 071430 Clorazepate Dipotassium Capsules, 3.75 mg ANDA 0717659 Danazol (Capsules USP, 200 mg ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg ANDA 071785 Oxazepam Capsules USP, 10 mg ANDA 071955 Oxazepam Capsules USP, 10 mg ANDA 071956 Oxazepam Capsules USP, 10 mg ANDA 071955 Oxazepam Capsules USP, 10 mg ANDA 071955 Dubate (clorazepate dipotassium) Tablets, 15 mg ANDA 071955 Oxazepam Capsules USP, 10 mg ANDA 071952 ANDA 07202 ANDA 07203 ANDA 072130 ANDA 072130 ANDA 072131 ANDA 072131 ANDA 072131 ANDA 072255 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072308 ANDA 072308 Fenoprofen Calcium Capsules USP, 200 mg ANDA 072308 Fenoprofen Calcium Capsules USP, 200 mg ANDA 072782 Prazosin HCl Capsules USP, 20 mg ANDA 072783 Prazosin HCl Capsules USP, 20 mg ANDA 072784 Prazosin HCl Capsules USP, 20 mg ANDA 072785 ANDA 072786 ANDA 073535 Proxicam Capsules USP, 5 mg ANDA 074762 ANDA 074503 ANDA 074503 ANDA 074503 ANDA 074504 ANDA 074504 ANDA 074505 ANDA 074702 Metaproterenol Sulfate Syrup, 10 mg/5 mL ANDA 074501 ANDA 074702 ANDA 074702 ANDA 074702 ANDA 074702 ANDA 074702 ANDA 074703 ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, 61% clored or color			
ANDA 071363 Meclofenamate Sodium Capsules USP, 100 mg Do. Soapco, Inc., P.O. Box 5490, Pleasanton, CA 94566. ANDA 071419 Brian Care (chlorhexidine gluconate) Topical Solution, 4% Clorazepate Dipotassium Capsules, 3.75 mg Do. NADA 071431 Clorazepate Dipotassium Capsules, 7.5 mg Do. NADA 071431 Clorazepate Dipotassium Capsules, 7.5 mg Do. NADA 071787 Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg Do. NADA 071787 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. NADA 071789 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. NADA 071789 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. NADA 071789 Co. Napa Do. N			·
ANDA 071429 Clorazepate Dipotassium Capsules, 3.75 mg Do. ANDA 071431 Clorazepate Dipotassium Capsules, 7.5 mg Do.			· · · · · · · · · · · · · · · · · · ·
ANDA 071431 Clorazepate Dipotassium Capsules, 7.5 mg Do. Do. ANDA 071431 Clorazepate Dipotassium Capsules, 15 mg Do. Do. Do. ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. Do. ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. Do. ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. Do. ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. Do. ANDA 071955 Oxazepam Capsules USP, 10 mg Do. Do. ANDA 071955 Oxazepam Capsules USP, 15 mg Do. Do. ANDA 071955 Oxazepam Capsules USP, 15 mg Do. Do. ANDA 071957 Oxazepam Capsules USP, 15 mg Do. Do. ANDA 071957 Oxazepam Capsules USP, 25 mg Do. Do. ANDA 071962 Leucovorin Calcium Tablets, EQ 10 mg base ANDA 072022 Triamterene and Hydrochlorothiazide Tablets, 75 mg/50 mg ANDA 072193 Maprotiline HCI Tablets USP, 25 mg Do. Do. ANDA 072193 Maprotiline HCI Tablets USP, 50 mg Do. Do. ANDA 072191 Maprotiline HCI Tablets USP, 50 mg Do. Do. ANDA 072191 Maprotiline HCI Tablets USP, 75 mg Do. Do. Do. ANDA 072191 Maprotiline HCI Tablets USP, 75 mg Do. Do. Do. ANDA 072190 Metaproterenol Sulfate Inhalation Solution, 5% Do. Do. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 4% ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 4% ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Prazosin HCI Capsules USP, 200 mg Do.			• • • • • • • • • • • • • • • • • • •
ANDA 071487 Clorazepate Dipotassium Capsules, 15 mg Do. ANDA 071588 Danazol Capsules USP, 200 mg Do. ANDA 071587 Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg Do. ANDA 071789 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Do. ANDA 071789 Gen-Xene (clorazepate dipotassium) Tablets, 15 mg Do. ANDA 071789 Gen-Xene (clorazepate dipotassium) Tablets, 15 mg Do. ANDA 071985 Gen-Xene (clorazepate dipotassium) Tablets, 15 mg Do. ANDA 071986 Oxazepam Capsules USP, 10 mg Merican Therapeutics, Inc. ANDA 071986 Do. ANDA 07222 Maprotiline HCI Tablets USP, 25 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 50 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 75 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 75 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 75 mg Do. ANDA 072190 Metaproterenol Sulfate Inhalation Solution, 5% Do. ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072309 Fenoprofen Calcium Capsules USP, 200 mg Do. ANDA 072309 Fenoprofen Calcium Capsules USP, 300 mg Do. ANDA 072783 Prazosin HCI Capsules USP, 5 mg Do. ANDA 072784 Prazosin HCI Capsules USP, 5 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Do. ANDA 074560 Flurbiprofen Tablets USP, 100 mg Do. ANDA 074560 Flurbiprofen Tablets, 250 mg and 500 mg Laboratories, Inc. ANDA 074881 Lopamidol Injection, 41%, 51%, 61%, and 76% Cock marging Cop., 927 South Curry Pike, P.O. Box 306 Bloomington, IN A7403. We Pharmaceuticals, Inc. Cock imaging Cop., 927 South Curry Pike, P.O. Box 306 Bloomington, IN A7403. We Pharmaceuticalia, Inc. Cock imaging Cop., 927 South Curry Pike, P.O. Box 306 Bloomington, IN A7403. We Pharmaceuticalia, Inc. We Pharmaceutical Con.			
ANDA 071569 Danazol Capsules USP, 200 mg Dc. ANDA 071787 Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg Dc. ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 15 mg Dc. ANDA 071955 Oxazepam Capsules USP, 10 mg Dc. ANDA 071955 Oxazepam Capsules USP, 15 mg Dc. ANDA 071956 Dc. ANDA 071965 Dc. ANDA 072022 Triamterne and Hydrochlorothiazide Tablets, 75 mg/50 mg ANDA 072130 Maprotiline HCl Tablets USP, 55 mg Dc. ANDA 072131 Maprotiline HCl Tablets USP, 55 mg Dc. ANDA 072130 Maprotiline HCl Tablets USP, 55 mg Dc. ANDA 072131 Maprotiline HCl Tablets USP, 57 mg Dc. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 4% Dc. ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg ANDA 072309 Fenoprofen Calcium Capsules USP, 200 mg Dc. ANDA 072309 Fenoprofen Calcium Capsules USP, 200 mg Dc. ANDA 072309 Fenoprofen Calcium Capsules USP, 200 mg Dc. ANDA 072309 Prazosin HCl Capsules USP, 2 mg Dc. ANDA 072782 Prazosin HCl Capsules USP, 2 mg Dc. ANDA 072783 Prazosin HCl Capsules USP, 2 mg Dc. ANDA 073535 Mctroderm (chlorhexidine gluconate) Topical Solution, 4% Dc. ANDA 074560 Flurbiprofen Tablets USP, 100 mg Dc. ANDA 074560 Flurbiprofen Tablets USP, 100 mg Mctromidol (metronidazole) Tablets, 250 mg and 500 mg Dc. ANDA 074660 Flurbiprofen Tablets USP, 100 mg Mctromidol Injection, 41%, 51%, 61%, and 76% Cook imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, 1N 47463, ANDA 075181 Prednisolone Solution Phosphate Oral Solution, EQ 5 mg Wchardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Dc. Dc. Dc. Dc. Dc. Dc. Dc. Dc. Dc. D			
ANDA 071878 Gen-Xene (clorazepate dipotassium) Tablets, 3.75 mg			
ANDA 071788 Gen-Xene (clorazepate dipotassium) Tablets, 7.5 mg" Do.			
ANDA 071955 Oxazepam Capsules USP, 10 mg Dase Oxazepam Capsules USP, 30 mg Do. ANDA 071957 Oxazepam Capsules USP, 30 mg Do. ANDA 071957 Do. ANDA 071958 Do. ANDA 071965 Ibu-tab (ibuprofen) Tablets, 800 mg ANDA 071965 Ibu-tab (ibuprofen) Tablets, 800 mg ANDA 072130 Maprotiline HCI Tablets USP, 25 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 50 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 50 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 50 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 75 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 75 mg Do. ANDA 072255 Microderm (chlorhexidine gluconate) Topical Solution, 4% Arlington, TX 76014. ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0,5%. ANDA 072308 Fenoprofen Calcium Capsules USP, 200 mg ANDA 072308 Fenoprofen Calcium Capsules USP, 200 mg ANDA 072382 Prazosin HCI Capsules USP, 600 mg ANDA 072782 Prazosin HCI Capsules USP, 2 mg Do. ANDA 07255 Metromical Hold of Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCI Capsules USP, 2 mg Do. ANDA 073535 Piroxicam Capsules USP, 5 mg MANDA 074523 Metromical Do. ANDA 074523 Metromical Do. ANDA 074523 Metromical Do. ANDA 074524 Prazosin HCI Capsules USP, 5 mg Do. ANDA 074525 Metromical Do. ANDA 074526 Prioxicam Capsules USP, 5 mg Do. ANDA 074527 Metromical Do. ANDA 074528 Prazosin HCI Capsules USP, 5 mg Do. Do. ANDA 074529 Metromical Do. ANDA 074520 Metromical Do. ANDA 074560 Flurbiprofen Tablets USP, 100 mg Metaproterenol Sulfate Syrup, 10 mg/5 mL Metromical Inc., P.O. Box 16598, Fort Worth, TX 76162. ANDA 074881 Iopamidol Injection, 41%, 51%, 61%, and 76% Bloomington, IN 47403. ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg We Pharmaceuticals, Inc.			
ANDA 071956 Oxazepam Capsules USP, 15 mg Do. ANDA 071962 Leucovorin Calcium Tablets, EQ 10 mg base Leucovorin Calcium Tablets, EQ 10 mg base MADA 071962 Ibu-tab (ibuprofen) Tablets, 800 mg Maprotiline HCI Tablets USP, 25 mg Maprotiline HCI Tablets USP, 55 mg Do. ANDA 072129 Maprotiline HCI Tablets USP, 55 mg Maprotiline HCI Tablets USP, 55 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 75 mg Do. ANDA 072130 Metaproterenol Sulfate Inhalation Solution, 5% Metaproterenol Sulfate Inhalation Solution, 5% Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072292 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Fenoprofen Calcium Capsules USP, 200 mg Do. ANDA 072308 Fenoprofen Calcium Capsules USP, 500 mg Do. ANDA 072782 Prazosin HCI Capsules USP, 1 mg Do. ANDA 072783 Prazosin HCI Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCI Capsules USP, 5 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Metaproterenol Sulfate Syrup, 10 mg/5 mL Metromidol (injection, 41%, 51%, 61%, and 76% Metaproterenol Solium Phosphate Oral Solution, Eq. 5 mg ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, Eq. 5 mg ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, Eq. 5 mg ANDA 075181 Do. ANDA 075181 Do. ANDA 075181 Do. ANDA 074523 Metaproterenol Sulfate Syrup, 10 mg/5 mL Metaproterenol Sulfate S			
ANDA 071967 Do. ANDA 071968 Leucovorin Calcium Tablets, 800 mg Do. ANDA 071965 Leucovorin Calcium Tablets, 800 mg Maprotiline HCl Tablets USP, 25 mg Maprotiline HCl Tablets USP, 50 mg Maprotiline HCl Tablets USP, 75 mg Metaproteronlo Sulfate Inhalation Solution, 5% Moroderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Fenoprofen Calcium Capsules USP, 200 mg Fenoprofen Calcium Capsules USP, 200 mg Prazosin HCl Capsules USP, 200 mg Do. ANDA 072309 Prazosin HCl Capsules USP, 1 mg Do. ANDA 072782 Prazosin HCl Capsules USP, 2 mg Do. ANDA 072783 Prazosin HCl Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCl Capsules USP, 5 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Metromidol (metronidazole) Tablets, 250 mg and 500 mg Metromidol (metronidazole) Tablets USP, 100 mg Metromidol (metronidazole) Tablets, 250 mg and 500 mg Metromidoles, 10c., P.O. Box 16598, Fort Workh, TX 76162. ANDA 074580 Flurbiprofen Tablets USP, 100 mg Metromidoles, 10c., P.O. Box 16598, Fort Workh, TX 76162. ANDA 074881 Iopamidol Injection, 41%, 51%, 61%, and 76% Metromidoles, 10c., P.O. B			•
ANDA 071965 ANDA 071965 ANDA 071965 ANDA 072022 ANDA 072129 ANDA 072129 ANDA 072130 ANDA 072131 ANDA 072131 ANDA 072130 ANDA 072255 ANDA 072255 ANDA 072255 ANDA 072255 ANDA 072255 ANDA 072256 ANDA 072292 ANDA 072292 ANDA 072307 ANDA 072292 ANDA 072308 ANDA 072308 ANDA 072308 ANDA 072782 ANDA 072782 ANDA 072782 ANDA 072783 ANDA 072784 ANDA 072784 ANDA 073535 ANDA 073535 ANDA 074523 ANDA 074580 ANDA 074580 ANDA 074580 ANDA 074580 ANDA 074581 ANDA 075181 ANDA 075181 ANDA 075181 ANDA 075181 ANDA 075181 BLUELOVOR Tablets, 800 mg ANDA 075181 ANDA			
ANDA 071965			
ANDA 072139 Maprotiline HCI Tablets USP, 25 mg Do. ANDA 072130 Maprotiline HCI Tablets USP, 50 mg Do. ANDA 072131 Maprotiline HCI Tablets USP, 55 mg Do. ANDA 072190 Metaproterenol Sulfate Inhalation Solution, 5% Do. ANDA 072190 Metaproterenol Sulfate Inhalation Solution, 5% Do. ANDA 072255 Microderm (chlorhexidine gluconate) Topical Solution, 4% Do. ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Sponge, 4% Fenoprofen Calcium Capsules USP, 200 mg Do. ANDA 072309 Fenoprofen Calcium Capsules USP, 300 mg Do. ANDA 072309 Frazosin HCI Capsules USP, 600 mg Prazosin HCI Capsules USP, 5 mg Do. ANDA 072784 Prazosin HCI Capsules USP, 5 mg Do. ANDA 073535 Prazosin HCI Capsules USP, 5 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. ANDA 074560 Flurbiprofen Tablets USP, 100 mg Metaproterenol Sulfate Syrup, 10 mg/5 mL Workh, TX 76162. ANDA 074702 Metaproterenol Sulfate Syrup, 10 mg/5 mL Workhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Do. Do. Do. Do. Do. Do. Do. Do. Do. D			
ANDA 072130 Maprotiline HCl Tablets USP, 50 mg Do. ANDA 0721910 Maprotiline HCl Tablets USP, 75 mg 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. Do. ANDA 072292 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Maprotiline MCl Capsules USP, 300 mg Prazosin HCl Capsules USP, 5 mg Do. ANDA 072782 Prazosin HCl Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCl Capsules USP, 5 mg Maprotiline MCl Capsules USP, 5 mg Metromidol (metronidazole) Tablets, 250 mg and 500 mg Metronidol (metronidazole) Tablets, 250 mg and 500 mg Metaproterenol Sulfate Syrup, 10 mg Metaproterenol Sulfate Syrup, 10 mg Metaproterenol Sulfate Syrup, 10 mg/S mL ANDA 074881 Lopamidol Injection, 41%, 51%, 61%, and 76% Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. Metaprotline HCl Tablets USP, 5 mg Do. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.	ANDA 072022		American Therapeutics, Inc.
ANDA 072191 Maprotiline HCl Tablets USP, 75 mg Do. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Do. ANDA 072308 Fenoprofen Calcium Capsules USP, 300 mg Prazosin HCl Capsules USP, 1 mg Do. Do. Prazosin HCl Capsules USP, 5 mg Do. Do. Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Metaproterenol Sulfate Syrup, 10 mg/s mL Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Do. American Therapeutics, Inc. Do. Do. Do. Do. Do. Do. Do. Do. Do. Do			
ANDA 072190 Metaproterenol Sulfate Inhalation Solution, 5% Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. ANDA 072292 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072292 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Do. ANDA 072308 Fenoprofen Calcium Capsules USP, 300 mg Do. ANDA 072309 Fenoprofen Calcium Subset Suspension HCI Capsules USP, 1 mg Do. ANDA 072782 Prazosin HCI Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCI Capsules USP, 5 mg Do. ANDA 073535 Prazosin HCI Capsules USP, 5 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. ANDA 074881 Metromidol Injection, 41%, 51%, 61%, and 76% Metaproterenol Solium Phosphate Oral Solution, 2% Metaproterials, Inc. Microderm (chlorhexidine gluconate) Topical Solution, 4% Do. Do. American Therapeutics, Inc. Do. Do. Do. Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. We Pharmaceuticals, Inc. Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. We Pharmaceuticals, Inc.		Maprotiline HCl Tablets USP, 50 mg	
ANDA 072255 Microderm (chlorhexidine gluconate) Topical Solution, 4% ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Sponge, 4% ANDA 072295 Microderm (chlorhexidine gluconate) Topical Sponge, 4% ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg Penoprofen Calcium Capsules USP, 800 mg Do. ANDA 072309 Fenoprofen Calcium Tablets USP, 600 mg Do. ANDA 072782 Prazosin HCI Capsules USP, 2 mg Do. ANDA 072783 Prazosin HCI Capsules USP, 5 mg Do. ANDA 072784 Prazosin HCI Capsules USP, 5 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. 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 306 Bloomington, IN 47403. WE Pharmaceuticals, Inc.		Metaproterenal Sulfate Inhalation Solution 5%	
ANDA 072292 Prevacare R (chlorhexidine gluconate) Topical Solution, 0.5%. ANDA 072295 Microderm (chlorhexidine gluconate) Topical Sponge, 4% Fenoprofen Calcium Capsules USP, 200 mg Fenoprofen Calcium Capsules USP, 300 mg Fenoprofen Calcium Tablets USP, 600 mg Do. ANDA 072309 ANDA 072782 ANDA 072783 ANDA 072783 Prazosin HCl Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCl Capsules USP, 2 mg Do. ANDA 073535 Provicem Capsules, 10 mg Do. ANDA 074523 Metromidol (metronidazole) Tablets, 250 mg and 500 mg delphia, PA 19124. ANDA 074560 Flurbiprofen Tablets USP, 100 mg Metaproterenol Sulfate Syrup, 10 mg/5 mL Metaproterenol Sulfate Syrup, 10 mg/5 mL Metaproterenol Sulfate Syrup, 10 mg/5 mL Metaproterenol Solium Phosphate Oral Solution, EQ 5 mg WE Pharmaceutical, Inc. ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg Arlington, TX 76014. Do. Arlington, TX 76014. Do. American Therapeutics, Inc. Do. Metaproteron Calcium Capsules USP, 2 mg Do. Do. Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. ANDA 074881 lopamidol Injection, 41%, 51%, 61%, and 76% Metaproteronol Sulfate Syrup, 10 mg/5 mL Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. WE Pharmaceuticals, Inc.	7111D71 072100	iniciaproteronor cunate initiatation columni, 575	
ANDA 072295			Arlington, TX 76014.
ANDA 072307 Fenoprofen Calcium Capsules USP, 200 mg		0.5%.	
ANDA 072308 Fenoprofen Calcium Capsules USP, 300 mg Do. ANDA 072309 Fenoprofen Calcium Tablets USP, 600 mg Do. ANDA 072782 ANDA 072783 ANDA 073535 Piroxicam Capsules USP, 5 mg Metromidol (metronidazole) Tablets, 250 mg and 500 mg ANDA 074560 ANDA 074702 ANDA 074881 Flurbiprofen Tablets USP, 100 mg ANDA 074881 Iopamidol Injection, 41%, 51%, 61%, and 76% ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg Do. Do. Do. Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. WE Pharmaceuticals, Inc.			
ANDA 072309 Fenoprofen Calcium Tablets USP, 600 mg Do. ANDA 072782 Prazosin HCl Capsules USP, 1 mg Do. ANDA 072784 Prazosin HCl Capsules USP, 2 mg Do. ANDA 072784 Prazosin HCl Capsules USP, 5 mg Do. ANDA 073535 Prioxicam Capsules, 10 mg			_ '
ANDA 072782			
ANDA 072783 ANDA 072784 ANDA 073535 ANDA 074523 ANDA 074560 ANDA 074702 ANDA 074881 ANDA 074881 Prazosin HCl Capsules USP, 2 mg Prazosin HCl Capsules USP, 5 mg Do. Do. Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Lopamidol Injection, 41%, 51%, 61%, and 76% ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg Do. Do. Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Phila delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. WE Pharmaceuticals, Inc.		,	
ANDA 074523 ANDA 074523 ANDA 074524 Metromidol (metronidazole) Tablets, 250 mg and 500 mg ANDA 074525 ANDA 074526 ANDA 074526 ANDA 074527 Metaproterenol Sulfate Syrup, 10 mg/5 mL ANDA 074881 ANDA 075181 Piroxicam Capsules, 10 mg		Prazosin HCl Capsules USP, 2 mg	
ANDA 074523 ANDA 074523 ANDA 074524 Metromidol (metronidazole) Tablets, 250 mg and 500 mg ANDA 074525 ANDA 074526 ANDA 074702 ANDA 074881 ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg Metromidol (metronidazole) Tablets, 250 mg and 500 mg delphia, PA 19124. Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. WE Pharmaceuticals, Inc.			
ANDA 074523 ANDA 074560 ANDA 074702 ANDA 074881 ANDA 075181 Metromidol (metronidazole) Tablets, 250 mg and 500 mg Laboratorios Applicaciones Farmaceuticas S.A. de CV, c/c Richard Hamer Association, Inc., P.O. Box 16598, Fort Worth, TX 76162. Theragen, Inc., 10 Lake Dr., East Windsor, NJ 08520. Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc. Cook Imaging Corp., 927 South Curry Pike, P.O. Box 306 Bloomington, IN 47403. WE Pharmaceuticals, Inc.	ANDA 073535	Piroxicam Capsules, 10 mg	
ANDA 074560 ANDA 074702 ANDA 074881 ANDA 075181 Flurbiprofen Tablets USP, 100 mg	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
ANDA 074702 ANDA 074881 ANDA 075181 Metaproterenol Sulfate Syrup, 10 mg/5 mL	ANDA 074560	Flurbiprofen Tablets USP, 100 mg	
ANDA 074881 lopamidol Injection, 41%, 51%, 61%, and 76%			Wockhardt EU Operations (Swiss) AG, c/o Morton Grove
ANDA 075181 Prednisolone Sodium Phosphate Oral Solution, EQ 5 mg WE Pharmaceuticals, Inc.	ANDA 074881	lopamidol Injection, 41%, 51%, 61%, and 76%	Cook Imaging Corp., 927 South Curry Pike, P.O. Box 3068,
	ANDA 075181		

TABLE 1—APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED—Continued

Application No.	Drug	Applicant
ANDA 075260	Tretinoin Topical Solution, 0.05%	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove
ANDA 075414	Nifedipine Extended-Release Tablets, 90 mg	Pharmaceuticals, Inc. 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 ANDA 080024	Albuterol Sulfate Inhalation Solution, EQ 0.083% base Sulfacel-15 (sulfacetamide sodium) Ophthalmic Solution, 15%.	Landela Pharmaceutical. 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 ANDA 080380 ANDA 080483	Soxazole (sulfisoxazole) Tablets, 500 mg	Alra Laboratories, Inc. Do. C and M Pharmacal, Inc., 1519 East 8 Mile Rd., Hazel
ANDA 080492	Reserpine Tablets, 0.1 mg and 0.25 mg	Park, MI 48030. Marshall Pharmacal Corp., 89 Michael St., South Hacken-
ANDA 080518	Dimenhydrinate Tablets, 50 mg	sack, NJ 07606. Alra Laboratories, Inc.
ANDA 080519	Diphenhydramine HCl Capsules, 25 mg and 50 mg	Do. 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 ANDA 080715	Diphenhydramine HCl Oral Solution, 12.5 mg/5 mL	Alra Laboratories, Inc.
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 ANDA 083088	Diphenhydramine HCl Capsules, 25 mg and 50 mg	MK Laboratories, Inc. Do.
ANDA 083264	Pentobarbital Sodium Capsules, 100 mg	Valeant Pharmaceuticals International.
ANDA 083286	Chlorpheniramine Maleate Tablets	Marshall Pharmacal Corp.
ANDA 083315	Procaine HCI Injection, 1% and 2%	Elkins Sinn Pharmaceutical Co., c/o ESI Lederle, 2 Esterbrook Ln., Cherry Hill, NJ 08003.
ANDA 083320 ANDA 083389	Acetazolamide Tablets, 250 mg Epinephrine and Lidocaine HCl Injection, 0.01 mg/mL and 1%.	Alra Laboratories, Inc., 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 ANDA 083525	Butabarbital Sodium Tablets, 16.2 mg	Marshall Pharmacal Corp. 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 ANDA 083863	Butabarbital Sodium Tablets, 32.4 mg	Marshall Pharmacal Corp. 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 ANDA 084188	Bethanechol Chloride Tablets, 25 mg	Do. Glenwood, Inc., 83 North Summit St., P.O. Box 518, Tenafly, NJ 07670.

TABLE 1—APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED—Continued

Application I	No.	Drug	Applicant
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 HCI 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.	Fleming and Co. Pharmaceuticals, Inc., 1600 Fenton Park Dr., Fenton, MO 63026.
		Aerolate JR (theophylline) Extended-Release Capsules, 130 mg.	
AND A 005407		Aerolate SR (theophylline) Extended-Release Capsules, 260 mg.	
ANDA 085107		Lygen (chlordiazepoxide HCl) Capsules, 5 mg	Alra Laboratories, Inc.
ANDA 085108		Lygen (chlordiazepoxide HCl) Capsules, 25 mg	Do.
ANDA 085125 ANDA 085235		Methyltestosterone Sublingual Tablets, 10 mg Chlordiazepoxide HCl Capsules	Tablicaps, Inc., P.O. Box 5555, Franklinville, NJ 08322. Abbott Laboratories, Pharmaceutical Products Division, 100 Abbott Park Rd., Abbott Park, IL 60064.
ANDA 085236		Chlordiazepoxide HCI 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 ANDA 085766		Cam-Metrazine (phendimetrazine tartrate) Tablets, 35 mg Atropine Sulfate and Diphenoxylate HCl Tablets, 0.025 mg/	Camall Co., Inc. Private Formulations, Inc.
ANDA OSESSO		2.5 mg. Brompheniramine Maleste Tablets	Leiner Health Products, 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			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.
		Tolbutamide Tablets, 500 mg	Alra Laboratories, Inc.
		Ona-Mast (phentermine HCI) Tablets, 8 mg	MM Mast and Co.
ANDA 086260		Hydrocortisone Cream, 2.5%	Ambix Laboratories, Division of Organics Corp. of America.
ANDA 086260 ANDA 086271		HOVEROPEOPE CHRIMANT 25%	Do.
ANDA 086260 ANDA 086271 ANDA 086272		Amitriatulina LICI Tableta 40	Alva I abayatayiga Ina
ANDA 086260 ANDA 086271 ANDA 086272 ANDA 086498		Amitriptyline HCl Tablets, 10 mg	Alra Laboratories, Inc.
ANDA 086260 ANDA 086271 ANDA 086272 ANDA 086498 ANDA 086499		Amitriptyline HCl Tablets, 10 mg	Do.
ANDA 086260 ANDA 086271 ANDA 086272 ANDA 086498 ANDA 086499 ANDA 086500		Amitriptyline HCl Tablets, 10 mg	Do. Do.
ANDA 086141 ANDA 086260 ANDA 086271 ANDA 086272 ANDA 086498 ANDA 086499 ANDA 086500 ANDA 086501		Amitriptyline HCl Tablets, 10 mg	Do. Do. Do.
ANDA 086260 ANDA 086271 ANDA 086272 ANDA 086498 ANDA 086499 ANDA 086500		Amitriptyline HCl Tablets, 10 mg	Do. Do. Do. Do.

TABLE 1-APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED-Continued

Application No.	Drug	Applicant
ANDA 086511	Ona-Mast (phentermine HCI) Capsules, 30 mg	MM Mast and Co.
ANDA 086516	Ona-Mast (phentermine HCI) 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-Re-	Shire Richwood, Inc.
	lease Capsules, 105 mg.	
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	Bedford Laboratories, Division of Ben Venue Laboratories,
	mg/vial, 500 mg/vial, 1 g/vial, and 2 g/vial.	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 HCI) Ophthalmic Solution, 0.5%	Optopics Laboratories Corp.
ANDA 087764	Oby-Trim (phentermine HCI) 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 HCI and	Do.
	promethazine HCl) Syrup, 5 mg/5 mL and 6.25 mg/5 mL.	
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	Do.
	mg/15 mg.	
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 October 22, 2021.

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy. [FR Doc. 2021–23075 Filed 10–21–21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent Commercialization License: CD28H Domain-Containing Chimeric Antigen Receptors and Methods of Use

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Ankarys Therapeutics Inc., located at

110 Cumberland Street, Suite 520, M5R 3V5, Toronto, Ontario, Canada, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before November 8, 2021 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Dawn Taylor-Mulneix, Technology Transfer and Patent Specialist, Technology Transfer and