4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5254]

Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of 249 abbreviated new drug applications (ANDAs) from multiple holders of those ANDAs and is announcing an opportunity for the ANDA holders to request a hearing on this proposal. The basis for the proposal is that these ANDA holders have repeatedly failed to file required annual reports for those ANDAs.

DATES: The ANDA holders may submit a request for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit all data, information, and analyses upon which the request for a hearing relies by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The request for a hearing may be submitted by the ANDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to https://www.regulations.gov, including any attachments to the request for a hearing, will be posted to the docket unchanged.

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. The request for a hearing must include the Docket No. FDA-2019-N-5254 for "Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 ANDAs; Opportunity for a Hearing." The request for a hearing will be placed in the docket and publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

The ANDA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions--To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as

a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Dockets Management Staff. Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in

the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-5254 for "Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 ANDAs; Opportunity for a Hearing." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-7920, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holders of approved ANDAs to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved ANDAs under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). The holders of the approved

ANDAs listed in the following table have repeatedly failed to submit the required annual reports and have not responded to the Agency's request, sent by certified mail, for submission of the reports.

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 milligrams (mg)/100 milliliters (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 060074	Penicillin G Potassium for Injection, 20,000,000 units/vial	Pfizer Laboratories, Division of Pfizer, Inc., 235 East 42nd St., New York, NY 10017
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	Ambix Laboratories, Division of Organics Corp. of America, 210

	Ointment	Orchard St., East Rutherford, NJ 07073
ANDA 060521	Humatin (paromomycin sulfate) Capsules USP, Equivalent to (EQ) 250 mg base	Parkedale Pharmaceuticals, Inc., 501 5th St., Bristol, TN 37620
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 060709	Oleandomycin Injection	Roerig, Division of Pfizer, Inc., 235 East 42nd St., New York, NY 10017
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 061034	Lincomycin HCl Powder	Pharmacia and Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49001
ANDA 061064	Nystatin Ointment	Lederle Laboratories, Division of American Cyanamid Co., 401 North Middletown Rd., Pearl River, NY 10965
ANDA 061087	Benzocaine, Oxytetracycline HCl, and Polymyxin B Sulfate Otic Solution	Pfizer Laboratories, Division of Pfizer, Inc.
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 061652	Oxytetracycline Capsules	Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950
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 061701	Tetracycline Syrup, 125 mg/5 mL	AH Robins Co., 1211 Sherwood Ave., Richmond, VA 23220
ANDA 061725	Cyclopar (tetracycline HCl) Capsules USP, 250 mg and 500 mg	Warner-Lambert Co.
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 061943	Chloramphenicol Ophthalmic Solution, 0.5%	Lederle Laboratories, Division of American Cyanamid Co., 1 Cyanamid Plaza, Wayne, NJ 07470
ANDA 062032	Erythromycin Stearate Tablets, EQ 250 mg base and EQ 500 mg base	Warner-Lambert Co.
ANDA 062085	Tetracycline HCl Capsules, 250 mg	MM Mast and Co., 4152 Ruple Rd., Cleveland, OH 44121
ANDA 062175	Tetracycline HCl Capsules, 250 mg	Warner-Lambert Co.
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 062215	Oxytetracycline HCl Capsules	Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965-1215

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 062869	Cephalexin Capsules USP, EQ 500 mg base	Jerome Stevens Pharmaceuticals Inc., 60 DaVinci Dr., Bohemia, NY 11716
ANDA 062870	Cephalexin Capsules USP, EQ 250 mg base	Do.
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 072196	Milophene (clomiphene citrate) Tablets, 50 mg	Milex Products, Inc., 5915 Northwest Highway, Chicago, IL 60631
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 073416	E-Z Scrub (chlorhexidine gluconate) Topical Sponge, 4%	Becton Dickinson Surgical System, 9450 South State St., Sandy, UT 84070
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 074988	Aspirin, Caffeine, and Orphenadrine	Jerome Stevens Pharmaceuticals, Inc.

	Citrate Tablets, 385 mg/30 mg/25 mg and 770 mg/60 mg/50 mg	
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 millicurie (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 081145	Aspirin and Methocarbamol Tablets, 325 mg/400 mg	Jerome Stevens Pharmaceuticals, Inc.
ANDA 083001	Triamcinolone Acetonide Aerosol Foam Emulsion	Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965-1215
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 084631	Quinidine Sulfate Tablets USP, 200 mg	Sandoz, Inc., 4700 Eon Dr., Wilson, NC 27893
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 084803	Chlorpromazine HCl Tablets, 10 mg	Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965-1215
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	Fleming and Co. Pharmaceuticals, Inc., 1600 Fenton Park Dr., Fenton,

	Aerolate JR (theophylline) Extended-Release Capsules, 130 mg Aerolate SR (theophylline) Extended-Release Capsules, 260 mg	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 085217	Acetaminophen and Codeine Phosphate Tablets, 325 mg/30 mg	Everylife
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 Hydrochloride Chewable Tablets	Camall Co., Inc., 60950 Van Dyke Ave., P.O. Box 218, Washington, MI 48094
ANDA 085638	Codeine, Aspirin, APAP Formula No. 4 (codeine phosphate, aspirin, and acetaminophen) Capsules, 60 mg/180 mg/150 mg	Scherer Laboratories, Inc., 2301 Ohio Dr., Suite 234, Plano, TX 75093
ANDA 085639	Codeine, Aspirin, APAP Formula No. 3 (codeine phosphate, aspirin, and acetaminophen) Capsules, 30 mg/180 mg/150 mg	Do.
ANDA 085640	Codeine, Aspirin, APAP Formula No. 2 (codeine phosphate, aspirin, and acetaminophen) Capsules, 15 mg/180 mg/150 mg	Do.
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	Private Formulations, Inc.

	Tablets, 0.025 mg/2.5 mg	
ANDA 085882	Duvoid (bethanechol chloride) Tablets, 50 mg	Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920
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 086262	Duvoid (bethanechol chloride) Tablets, 10 mg	Chartwell RX Sciences, LLC
ANDA 086263	Duvoid (bethanechol chloride) Tablets, 25 mg	Do.
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.
ANDA 204472	Fludeoxyglucose F-18 Injection USP, 20-300 mCi/mL	MIPS Cyclotron and Radiochemistry Facility, 1201 Welch Rd., Rm. PS049, Stanford, CA 94305
ANDA 204517	Sodium Fluoride F-18 Injection, 10-200 mCi/mL	Do.
ANDA 204535	Ammonia N-13 Injection USP, 3.75-37.5	Do.

	mCi/mL	

Therefore, under §§ 314.150(b)(1) and 314.200 (21 CFR 314.150(b)(1) and 314.200), notice is given to the holders of the approved ANDAs listed in the table and to all other interested persons that the Director of CDER proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) withdrawing approval of the ANDAs and all amendments and supplements to them on the grounds that the ANDA holders have failed to submit reports required under §§ 314.81 and 314.98.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the ANDA holders are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for an administrative determination, all issues relating to the legal status of the drug products covered by these ANDAs.

An ANDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see DATES and ADDRESSES) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see DATES and ADDRESSES). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, the notice of participation and request for a hearing; the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the

ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at https://www.regulations.gov.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: January 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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