Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2485]

Fougera Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 061467	Pyocidin-Otic (hydrocortisone and polymyxin B sulfate) Otic Solution, 5 milligrams (mg)/10,000 units per milliliter (mL).	Fougera Pharmaceuticals, Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
ANDA 061653	Tetrex (tetracycline phosphate complex) Capsules, Equivalent to (EQ) 100 mg Hydrochloride (HCl), EQ 250 mg HCl and EQ 500 mg HCl.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
ANDA 061658	Bristacycline (tetracycline HCl) Capsules, 250 mg and 500 mg	Do.
ANDA 061711	Penicillin V Potassium Tablets	Do.
ANDA 061721	Ampicillin Capsules, 250 mg and 500 mg	Do.
ANDA 061726	Azotrex (phenazopyridine HCl, sulfamethizole and tetracycline phosphate complex) Capsules, 50 mg/250 mg/125 mg.	Do.
ANDA 061790	Hetacillin Potassium	Do.
ANDA 061887	Bristamycin (erythromycin stearate) Tablets, EQ 250 mg base	Do.
ANDA 061888	Bristacycline (tetracycline HCl) Capsules, 250 mg and 500 mg	Do.
ANDA 061889	Tetrex (tetracycline phosphate complex) Capsules, EQ 250 mg HCl and EQ 500 mg HCl.	Do.
ANDA 061890	Azotrex (phenazopyridine HCl, sulfamethizole, and tetracycline) Capsules, 50 mg/250 mg/125 mg.	Do.
ANDA 061891	Tetrex-S (tetracycline) Syrup, 125 mg/5 mL	Do.
ANDA 061975	Cephradine Powder for Injection	Do.
ANDA 062168	Cephradine Tablets	Do.
ANDA 062259	Amphotericin B for Use in Parenteral Products	Do.
ANDA 062543	Mycolog (nystatin, neomycin sulfate, gramicidin, and triamcinolone acetonide) Ointment.	Do.
ANDA 071793	Foamcoat (aluminum hydroxide; magnesium trisilicate) Chewable Tablets, 80 mg/20 mg (OTC).	Guardian Drug Co., 2 Charles Court, Dayton, NJ 08810.
ANDA 072035	Nuprin (ibuprofen) Tablets, 200 mg	Bristol-Myers Squibb Co.
ANDA 072036	Nuprin (ibuprofen) Tablets, 200 mg	Do.
ANDA 074911	Phrenilin with Caffeine and Codeine (acetaminophen, butalbital, caffeine, and codeine phosphate) Capsules, 325 mg/50 mg/40 mg/30 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 074944	Atracurium Besylate Injection, 10 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075206	Cytosar-U (cytarabine) for Injection USP, 100 mg/vial, 500 mg/vial, 1 gram (g)/vial, and 2 g/vial.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 077337	Rosiglitazone Maleate and Metformin HCl Tablets, EQ 1 mg base/500 mg, EQ 2 mg base/500 mg, EQ 4 mg base/500 mg, EQ 2 mg base/1 g, and EQ 4 mg base/1 g.	Do.
ANDA 077930	Meloxicam Tablets, 7.5 mg and 15 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 080658	Procaine HCl Injection, 1% and 2%	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083128	Hydrocortisone Acetate Injectable Suspension, 25 mg/mL	Do.
ANDA 090181	Ifosfamide for Injection, 1 g/20 mL and 3 g/60 mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 7, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on September 7, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2702]

Merck Sharp & Dohme Corporation, et al.; Withdrawal of Approval of Four New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of four new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 005619	Aminohippurate Sodium (PAH) 20% sterile solution Injection, 2 grams in 10 milliliter (mL) vials.	Merck Sharp & Dohme Corp., Subsidiary of Merck & Company, Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 008506	Hydrocortone (hydrocortisone) Tablets USP, 10 milligrams (mg) and 20 mg.	Do.
NDA 011891	Durabolin (nandrolone phenpropionate) Injection, 25 mg/mL and 50 mg/mL.	Organon USA, Inc., Subsidiary of Merck & Company, Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 020301	Ortho-Cept (desogestrel and ethinyl estradiol) Tablets USP, 0.15 mg/0.03 mg (21-Day and 28-Day Regimens).	Janssen Pharmaceuticals, Inc., 920 U.S. Hwy. 202, P.O. Box 300, Raritan, NJ 08869–0602.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 7, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on September 7, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1692]

Elemental Impurities in Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Elemental Impurities in Drug Products.'' This guidance finalizes the draft guidance issued July 1, 2016, which provides recommendations regarding the control of elemental impurities of human drug products marketed in the United States consistent with the implementation of International Council for Harmonisation (ICH) guidance for industry entitled ''Q3D Elemental Impurities'' (ICH Q3D). This guidance will also assist manufacturers of compendial drug products in responding to the issuance of the United States Pharmacopeia (USP) requirement for the control of elemental impurities.

DATES: The announcement of the guidance is published in the **Federal Register** on August 8, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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