3. Regulatory science initiatives that FDA should begin to consider in FY 2019, including, for example:

a. Scientific challenges in the evaluation of sensitization for transdermal systems and

b. The development of alternative approaches to in vivo bioequivalence studies to evaluate product equivalence.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2020 regulatory science initiatives. Information concerning the regulatory science initiatives for generic drugs can be found at *https://www.fda.gov/gdufaregscience.*

III. Participating in the Public Workshop

Registration: To register for the public workshop, please email complete contact information for each attendee—including the attendee's name, title, affiliation, address, email, and telephone number—to *GDUFARegulatoryScience@fda.hhs.gov.* Please also indicate in the email whether attendance will be by webcast or in person.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by April 1, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**) no later than April 1, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments (and requests to participate in the focused sessions). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 8, 2019. All requests to make oral presentations must be received by the close of registration on April 1, 2019, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than April 22, 2019, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Please register online by April 1, 2019, 11:59 p.m. Eastern Time to attend the workshop remotely. Please note that remote attendees will not be able to speak or make presentations during the public comment period or during any other session of the workshop. To join the workshop via the webcast, please go to *https://collaboration.fda.gov/gdufa2019/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov* or at *https://www.fda.gov/gdufaregscience.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufaregscience.*

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01067 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 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 23 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 7, 2019.

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 applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process 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 062117	Cephalexin for Oral Suspension USP, Equivalent to (EQ) 100 milligrams (mg) base/milliliter (mL), EQ 125 mg base/5 mL, and EQ 250 mg base/5 mL.	Facta Farmaceutici S.p.A., c/o Interchem Corp., 120 Route, 17 North, Paramus, NJ 07652.
ANDA 062508	Erymax (erythromycin) Topical Solution USP, 2%	Merz North America, 6501 Six Forks Rd., Raleigh, NC 27615.
ANDA 075369	Enalapril Maleate Tablets USP, 10 mg and 20 mg	Krka, tovarna zdravil, d.d., Novo mesto, Slovenia, c/o KRKA USA, LLC, 4216 Cravens Point Rd., Wilmington, NC 28409.
ANDA 075370	Enalapril Maleate Tablets USP, 2.5 mg and 5 mg	Do.

Application No.	Drug	Applicant
ANDA 077895	Ursodiol Capsules USP, 300 mg	Impax Laboratories, LLC, 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 078810	Oxaliplatin for Injection, 50 mg/vial and 100 mg/vial	Fresenius Kabi Oncology Plc., c/o Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 080420	Lidocaine Hydrochloride (HCl) Injection USP, 1%, 1.5%, and 2%.	Lyphomed, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160.
ANDA 080421	Procaine HCl Injection USP, 1% and 2%	Do.
ANDA 083083	Lidocaine HCl Injection USP, 1% and 2%	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101.
ANDA 083744	Lidocaine HCl Injection USP, 0.5%, 1%, 1.5%, and 2%	Tera Pharmaceuticals, Inc., 6920 Stanton Ave., Buena Park, CA 90621.
ANDA 083907	Lidocaine HCl With Epinephrine Injection USP	Do.
ANDA 084571	Lidocaine HCl Injection, 10 mg/20 mL and 10 mg/50 mL	Knoll Pharmaceuticals, 30 North Jefferson Rd., Whippany, NJ 07981.
ANDA 084572	Lidocaine HCl Injection, 20 mg/20 mL and 20 mg/50 mL	Do.
ANDA 084720	Lidocaine HCl and Epinephrine Injection USP, 2%; 0.01 mg/mL.	Naska Pharmacal Co., Inc., Riverview Rd., P.O. Box 898, Lincolnton, NC 28093.
ANDA 084732	Lidocaine HCl and Epinephrine Injection USP, 2%; 0.02 mg/mL.	Do.
ANDA 084947	Alphacaine (lidocaine) Ointment, 5%	Carlisle Laboratories, Inc., 404 Doughty Blvd., Inwood, NY 11696.
ANDA 085037	Lidocaine HCl Injection USP, 1% and 2%	Akorn, Inc., P.O. Box 1220, Decatur, IL 62525.
ANDA 085677	Cortisone Acetate Injectable Suspension USP, 25 mg/mL and 50 mg/mL.	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043.
ANDA 088051	Thalitone (chlorthalidone) Tablets USP, 25 mg	Casper Pharma LLC, 2 Tower Center Blvd., Suite 1101C, East Brunswick, NJ 08816.
ANDA 089688	Lidocaine HCl Topical Solution USP, 4%	Paco Research, Corp., 1705 Oak St., Lakewood, NJ 08701.
ANDA 091212	Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg.	Krka, tovarna zdravil, d.d., Novo mesto, c/o KRKA USA, LLC.
ANDA 091377	Vancomycin HCl for Injection USP, EQ 500 mg base/vial and EQ 1gram (g) base/vial.	Xellia Pharmaceuticals ApS, c/o Xellia Pharmaceuticals USA, LLC, 8841 Wadford Dr., Raleigh, NC 27616.
ANDA 206243	Vancomycin HCl for Injection USP, EQ 5 g base/vial and EQ 10 g base/vial (Pharmacy Bulk Package).	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 7, 2019. 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 March 7, 2019, 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: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01129 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1987–D–0240 (formerly 87D–0315)]

Neomycin Sulfate for Prescription Compounding; Withdrawal of Approval of One Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 061579 for nonsterile neomycin sulfate powder for prescription compounding. The basis for the withdrawal is that the product is no longer considered safe as labeled due to clinical evidence that systemic exposure to neomycin sulfate can induce significant toxicity, including ototoxicity (manifested as sensorineural hearing loss), nephrotoxicity, and neuromuscular blockade. The holder of this ANDA has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of February 5, 2019.

FOR FURTHER INFORMATION CONTACT: Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6286, Silver Spring, MD 20993–0002, 240–402–1748.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 1988, FDA published four documents arising out of the Agency's finding that systemic absorption of neomycin sulfate can induce significant toxicity, including ototoxicity (manifested as sensorineural hearing loss), nephrotoxicity, and neuromuscular blockade (see generally 53 FR 12644; 53 FR 12658; 53 FR 12662; and 53 FR 12664 (April 15, 1988)). Two of the four documents were issued under docket numbers FDA–1979–N–0220 and FDA–1987–D–0240 and related to nonsterile neomycin sulfate for prescription compounding.[1]

Under docket number FDA–1979–N–0220, FDA published a final rule amending the antibiotic drug

[1] These documents were originally assigned docket numbers 79N–0155, and 87D–0315. The numbers were changed to FDA–1979–N–0220 and FDA–1987–D–0240, respectively, as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008. The other two documents were issued under docket number FDA–1979–N–0256 (formerly 79N–0151) and related to neomycin sulfate in sterile vials for parenteral use.