

2021. Since the project's implementation, the grantee has made satisfactory progress toward its approved work plan.

This supplemental funding is intended to enhance NCOA's existing work—enabling them to provide responsive support for community-based organizations during the COVID-19 pandemic by piloting the remote/virtual delivery of falls prevention interventions.

As a well-established and trusted organization in the aging and disability networks, NCOA is uniquely positioned to complete the work called for under this project. Their current grant has two primary goals: (1) To provide public education on the risk of falls and how to prevent them; and (2) support the implementation and dissemination of evidence-based falls prevention programs. To accomplish these goals, NCOA serves as the national leader in falls prevention, reaching millions of professionals, older adults, individuals with disabilities, and their families each year through Falls Prevention Awareness Day and other public awareness activities and events. They also provide technical assistance for organizations implementing falls prevention programs, including one-on-one consultation, national conferences, and webinars. They have a comprehensive, interactive website with tools and resources, including—but not limited to—issues briefs, tip sheets,

policy and practice models, and toolkits. They have also presented to the aging and disability networks locally and on a national level, and have developed substantive partnerships with program developers, organizations, universities.

Establishing an entirely new grant project at this time would be potentially disruptive to the work needed to ensure the continued availability of falls prevention programs. If this supplement were not provided, ACL grantees and the hundreds community-based organizations across the nation who provide many of these falls prevention interventions would be unable to do so due to the COVID-19 pandemic.

Dated: July 8, 2020.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1227]

**Roerig Division of Pfizer Inc., et.al.;
Withdrawal of Approval of 10
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 10 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 August 20, 2020.

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, 240-402-6980, Martha.Nguyen@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 060709	Oleandomycin Injection	Roerig Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
ANDA 061087	Benzocaine, Oxytetracycline Hydrochloride (HCl), and Polymyxin B Sulfate Otic Solution.	Pfizer Laboratories, Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
ANDA 061725	Tetracycline HCl Capsules, 250 milligrams (mg) and 500 mg.	Warner Chilcott Division of Warner Lambert-Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
ANDA 061943	Chloramphenicol Ophthalmic Solution, 0.5%	Lederle Laboratories, Division of American Cyanamid Co., 1 Cyanamid Plaza, Wayne, NJ 07470.
ANDA 062175	Tetracycline HCl Capsules, 250 mg	Warner Chilcott Division of Warner Lambert-Pfizer, Inc.
ANDA 062215	Oxytetracycline HCl Capsules	Lederle Laboratories, Division of American Cyanamid Co.
ANDA 076203	Ribavirin Capsules, 200 mg	Kadmon Pharmaceuticals, LLC, 119 Commonwealth Dr., Warrendale, PA 15086.
ANDA 077456	Ribavirin Tablets, 200 mg, 400 mg, and 600 mg	Do.
ANDA 084669	Chlorpropamide Tablets, 250 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038.
ANDA 201750	Articaine HCl and Epinephrine Bitartrate for Injection, 4%; Equivalent to (EQ) 0.017 mg base/1.7 milliliters (mL); (4%; EQ 0.01 mg base/mL).	Hansamed Ltd., 4761 Tara Ct., West Bloomfield, MI 48323.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 20, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. 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 August 20, 2020 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: July 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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