Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1349]

Mikart, LLC, et al.; Withdrawal of Approval of 31 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 31 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 11, 2022.

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 040846	Hydrocodone Bitartrate and Acetaminophen Tablets, 325 milligrams (mg); 2.5 mg.	Mikart, LLC, 1750 Chattahoochee Ave. NW, Atlanta, GA 30318.
ANDA 040851	Benzonatate Capsules, 100 mg, 150 mg, and 200 mg	Do.
ANDA 072903	Ibuprofen Tablets, 200 mg	ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623.
ANDA 073519	Tolmetin Sodium Capsules, Equivalent to (EQ) 400 mg base	Do.
ANDA 074267	Guanabenz Acetate Tablets, EQ 4 mg base and EQ 8 mg base	Do.
ANDA 074498	Indapamide Tablets, 1.25 mg and 2.5 mg	Do.
ANDA 074840	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 074844	Etodolac Capsules, 200 mg and 300 mg	Do.
ANDA 075212	Ranitidine Hydrochloride (HCl) Tablets, EQ 75 mg base	Do.
ANDA 076030	Flecainide Acetate Tablets, 50 mg, 100 mg, and 150 mg	Do.
ANDA 076086	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg	Do.
ANDA 077426	Ranitidine HCl Tablets, EQ 150 mg base and EQ 300 mg base	Do.
ANDA 077641	Zonisamide Capsules, 25 mg, 50 mg, and 100 mg	Do.
ANDA 077979	Alprazolam Extended Release Tablets, 0.5 mg, 1 mg, 2 mg, and 3 mg.	Do.
ANDA 085269	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 085740	Meclizine HCl Tablets, 25 mg	Do.
ANDA 087296	Chlorthalidone Tablets, 25 mg	Do.
ANDA 088164	Chlorthalidone Tablets, 25 mg	Do.
ANDA 088641	Glucamide Tablets, 250 mg	Do.
ANDA 088732	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 088768	Chlorpropamide Tablets, 100 mg	Do.
ANDA 088826	Chlorpropamide Tablets, 250 mg	Do.
ANDA 090572	Cetirizine HCl, Syrup 5 mg/5 milliliters (mL)	Tris Pharma, Inc., 2031 U.S. Hwy. 130, Suite D, Monmouth Junction, NJ 08852.
ANDA 090906	Levetiracetam Tablets, 250 mg, 500 mg, 750 mg, and 1 gram (gm)	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd., Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 201944	Potassium Chloride Extended Release Capsules, 8 milliequivalent (mEq) and 10 mEq.	Tris Pharma, Inc.
ANDA 202095	Levetiracetam Extended Release Tablets, 500 mg and 750 mg	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd.
ANDA 202246	Levonorgestrel Tablets, 1.5 mg	Alvogen, Inc., 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 203298	Calcium Acetate Capsules, 667 mg	Alvogen PB Research and Development, U.S. Agency for Lotus Pharmaceutical Co., Ltd.
ANDA 204180	Amiloride HCl Tablets, 5 mg	USpharma Windlas, LLC, 115 Blue Jay Dr., Suite 101, Liberty, MO 64068.
ANDA 205442	Linezolid Injection, 600 mg/300 mL (2 mg/mL)	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 205790	Prasugrel Tablets, EQ 5 mg base and EQ 10 mg base	USpharma Windlas, LLC.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 11, 2022. 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 11, 2022 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 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1729]

Revocation of Emergency Use of a Drug During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Fresenius Kabi USA, LLC (Fresenius Kabi), for Fresenius Propoven 2% Emulsion. FDA revoked the Authorization on May 10, 2022, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of May 10, 2022.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 8, 2020, FDA issued an Authorization (EUA 050) to Fresenius Kabi for Fresenius Propoven 2% Emulsion, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on September 11, 2020 (85 FR 56231), as required by section 564(h)(1) of the FD&C Act. The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on April 8, 2022, Fresenius Kabi requested revocation of, and on May 10, 2022, FDA revoked, the Authorization for the Fresenius Propoven 2% Emulsion. Because Fresenius Kabi notified FDA that it does not intend to offer the Fresenius Propoven 2% Emulsion in the United States anymore and requested FDA revoke the EUA for the Fresenius Propoven 2% Emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for Fresenius Kabi's Fresenius Propoven 2% Emulsion. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.