FDA ADVISORY
No. 20240637

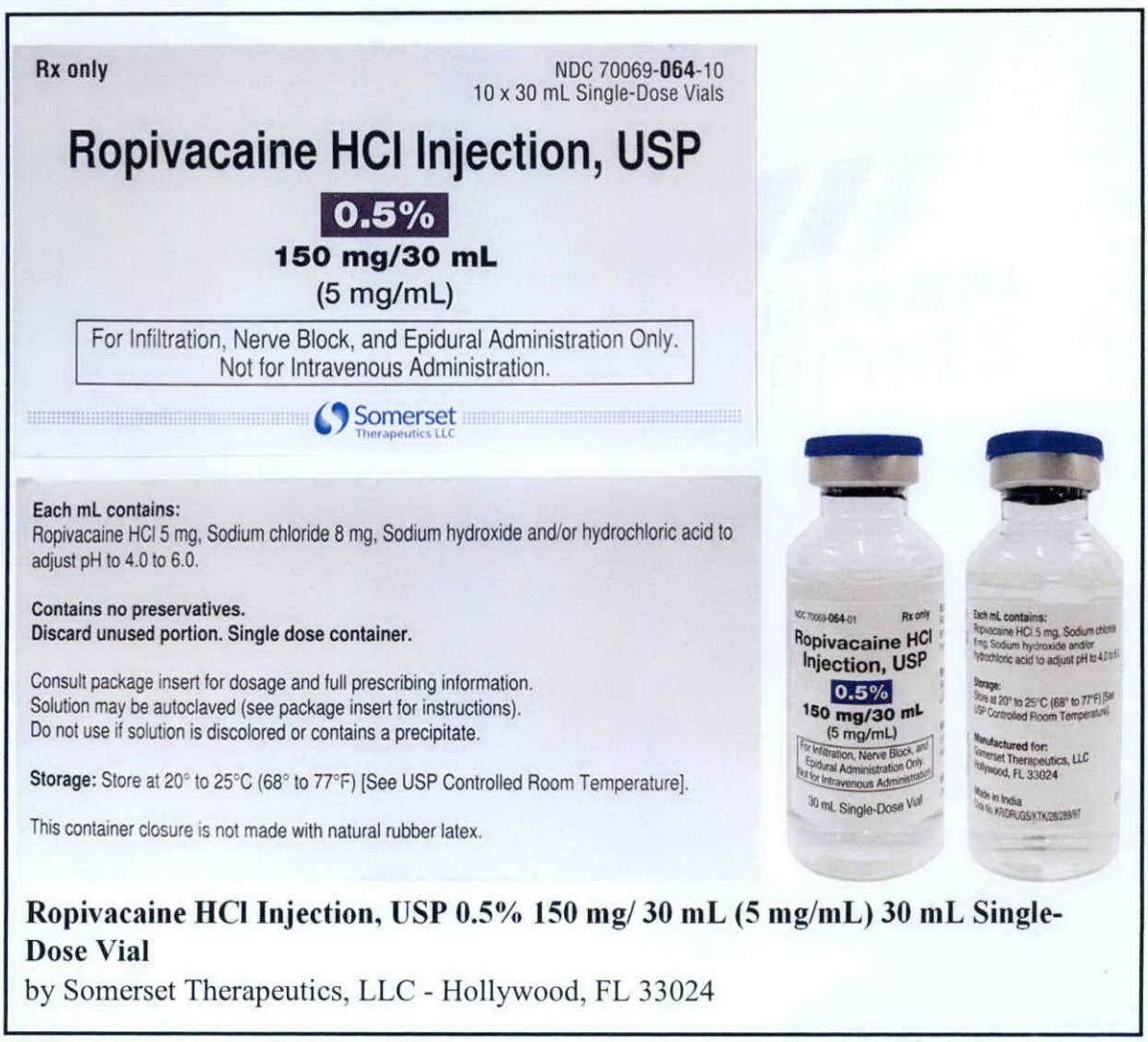
08 APR 2024

TO : **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT : **Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:**

1. **Ropivacaine HCl Injection, USP 0.5% 150 mg/ 30 mL (5 mg/mL) 30 mL Single-Dose Vial**
2. **Diprivan® (Propofol) Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL) 20 mL Vial**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



Ropivacaine HCl Injection, USP 0.5% 150 mg/ 30 mL (5 mg/mL) 30 mL Single-Dose Vial
by Somerset Therapeutics, LLC - Hollywood, FL 33024

Figure 1. Unregistered drug product

Diprivan® (Propofol) Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL) 20 mL Vial

Traded by: Frensenius Kabi - Lake Zurich, IL

Figure 2. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at **https://verification.fda.gov.ph**.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

DTN: 20240216153204