Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY

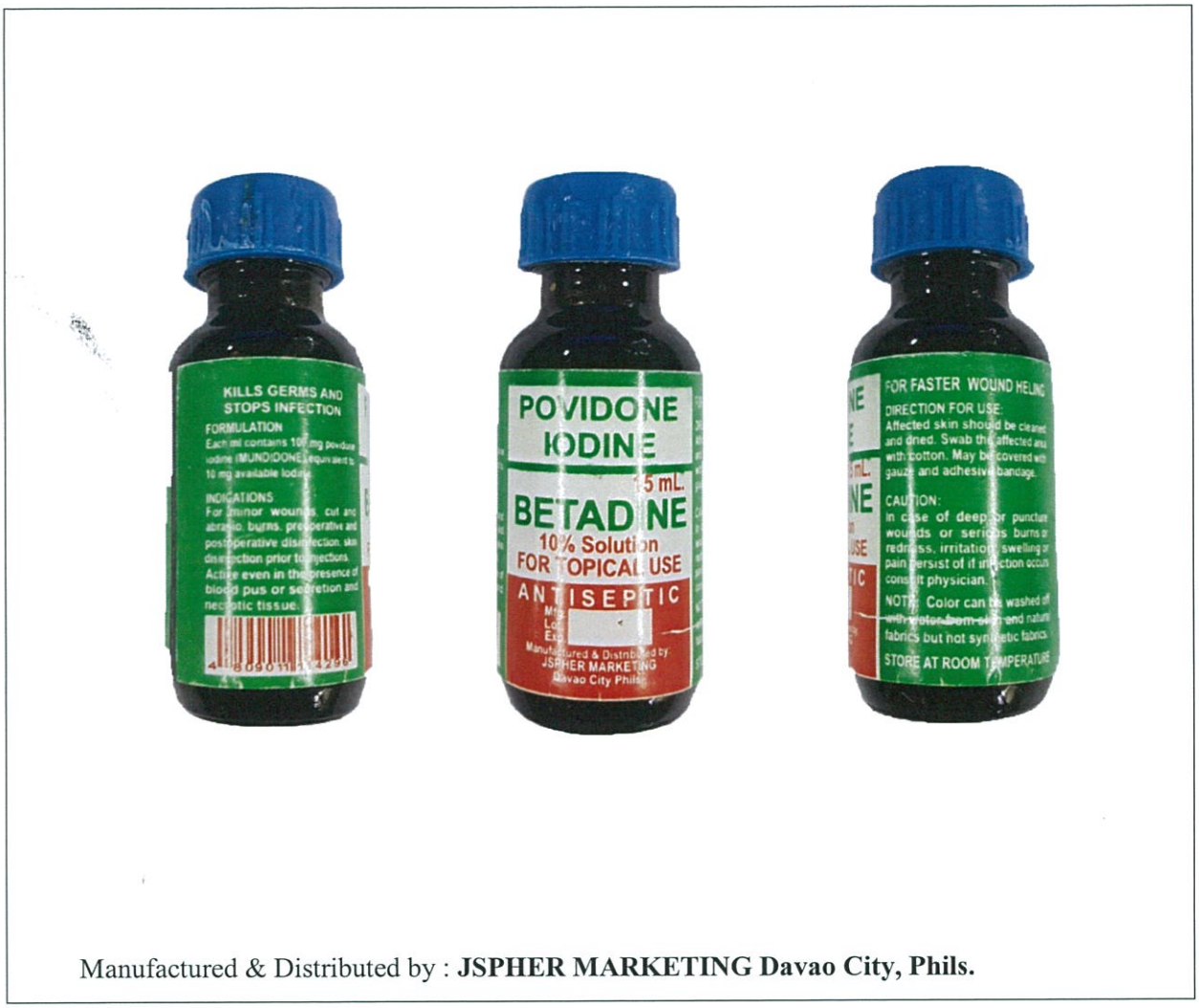
No. 2019-093

03 APR 2019

TO: **ALL HEALTHCARE PROFESSIONALS, LOCAL HEALTH CENTERS, HEALTH INSTITUTIONS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Versions of POVIDONE-IODINE (BETADINE) 10% Solution 15mL**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit versions of POVIDONE-IODINE (BETADINE) 10% Solution 15mL



Manufactured & Distributed by : **JSPHER MARKETING Davao City, Phils.**

Figure 1. Verified counterfeit version 1 of Betadine 10% Solution (in amber glass bottle)

Distributed by: **SOL-TAN MARKETING Davao City, Phils.**

Figure 2. Verified counterfeit version 2 of Betadine 10% Solution (in amber glass bottle)

Manufactured & Distributed by: **SULTAN MARKETING Cebu City, Phils.**

Figure 3. Verified counterfeit version 3 of Betadine 10% Solution (in amber glass bottle)

Figure 4. Verified counterfeit version 4 of Betadine 10% Solution (in amber glass bottle)

The FDA, together with the Marketing Authorization Holder (MAH), MUNDIPHARMA DISTRIBUTION GmbH, have verified that the above mentioned products are counterfeit.

Figure 5. Authentic drug product of Betadine 10% Solution 15mL (DRHR-341)

Note: The current packaging of the authentic product is in Mustard HDPE Plastic Bottle with induction liner and PP cap.

All healthcare professionals, local health centers, health institutions and the general public are hereby warned of these counterfeit versions of drug product in the market which pose potential danger or injury to consumers. Consumers, distributors and retailers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing these verified counterfeit versions of drug product with the aforementioned features. The importation, selling or offering for sale, brokering, donating or possession without proof of legitimate purchase of such are in direct violation of Republic Act No. 9711, or the Food and Drug Administration Act of 2009, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs, therefore a penalty shall be imposed.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that counterfeit products are not sold, made available or used 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 suspected unregistered or counterfeit health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02)809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **www.fda.gov.ph/adr-report-new** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

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Director General

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