



FDA ADVISORY
No. **2018-082**

16 MAR 2018

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug Product Sevoflurane (Sevorane) 100% Liquid for Inhalation

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Sevoflurane (Sevorane) 100% Liquid for Inhalation:



Sevoflurane (Sevorane) 100% Liquid For Inhalation 250 mL

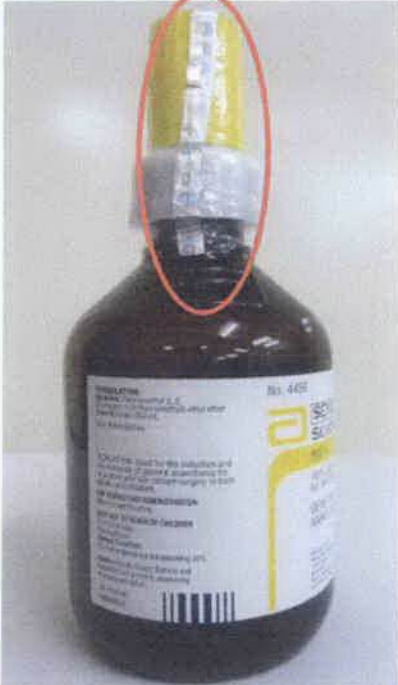

Manufactured by: Aesica Queensborough Ltd. – Queensborough, Kent, ME 11 5EL, United Kingdom

Imported by: Abbott Laboratories (Philippines) – 102 EDSA cor. Madison St., Mandaluyong City

Figure 1. Verified counterfeit/fake Sevoflurane (Sevorane) 100% Liquid for Inhalation



The FDA, together with the Marketing Authorization Holder (MAH), Abbott Laboratories Philippines, have verified that the abovementioned sample drug product is counterfeit. The comparisons of the collected product and the registered and authentic one are as follows:

AUTHENTIC	COUNTERFEIT
<ul style="list-style-type: none"> • Presence of shrink band security tape that changes color from orange to green when tilted 	<ul style="list-style-type: none"> • No shrink band security tape 
<ul style="list-style-type: none"> • Volume and weight of sample are similar with that of the retention sample 	<ul style="list-style-type: none"> • Bottles appeared to be overfilled with very little air inside • Weight of the bottle is below the expected weight
<ul style="list-style-type: none"> • Active ingredient (Sevoflurane) content is within specifications 	<ul style="list-style-type: none"> • Sample contains around 83% - 88% water

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers 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 of this verified counterfeit drug product with the abovementioned features. The importation, selling or offering for sale of such is 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 this counterfeit product is 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 and/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.


NELA CHARADE G. PUNO, RPh
Director General



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