



16 JUL 2019

FDA ADVISORY
No. 2019-195

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unregistered Medical Device "DUNHAME NEBULIZER MASK WITH CHAMBER AND TUBING"

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the unregistered medical device:



Figure 1. Unregistered Dunhame Nebulizer Mask with Chamber and Tubing



The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not yet been issued. Pursuant to the 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, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since this unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

In light of the foregoing, the public is advised not to purchase the violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device until CPR is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

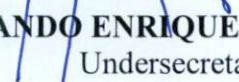
All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that this product is not sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at cdrhr@fda.gov.ph, or call **(02) 857-1900 loc. 8301**.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


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DTN 20190403115121