Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

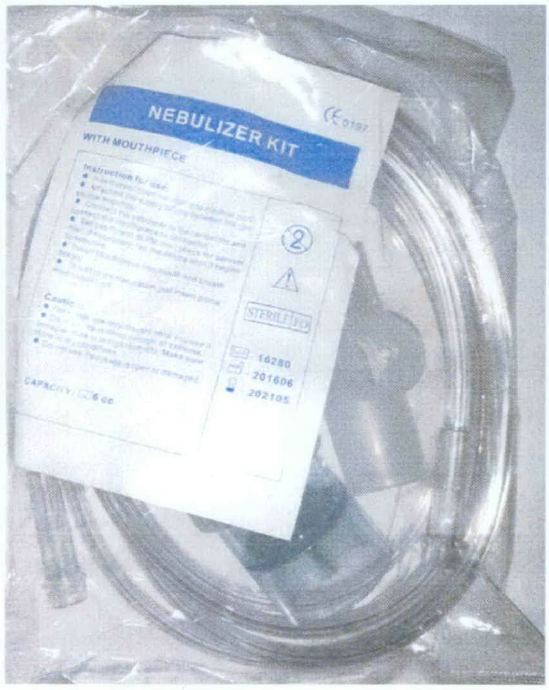
27 FEB 2019

FDA ADVISORY
No. 2019-052

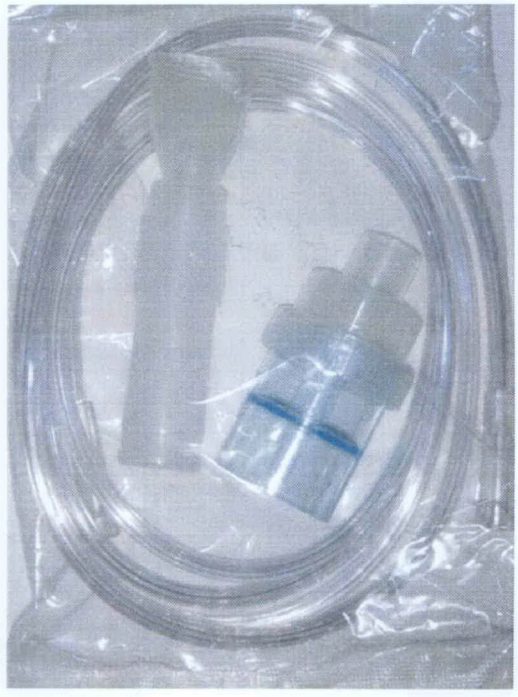
TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unregistered Medical Device (Nebulizer Kit with Mouthpiece)**

The Food and Drug Administration (FDA) advises all concerned healthcare professionals and the public against the purchase and use of the nebulizer kit with mouthpiece shown below:



Front of product packaging



Back of product packaging

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FDA post-marketing surveillance activities have verified that the nebulizer kit mentioned above has not gone through the registration process of the agency and has not been issued with Certificate of Product Registration (CPR).

Pursuant to the provisions of Republic Act 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 any health product without the proper authorization are prohibited.

Since the abovementioned product did not undergo the evaluation process of the FDA, the agency cannot guarantee its quality and safety.

In this regard, the public is hereby advised not to purchase the above-mentioned violative product. All concerned establishments are warned not to advertise, sell or distribute the said product until such has been issued with the corresponding Certificate of Product Registration, otherwise, regulatory actions and sanctions shall be strictly pursued.

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

For more information and inquiries, please email us at **info@fda.gov.ph.** To report continuous sale or distribution of the above medical device, utilize our online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**, or email us via **report@fda.gov.ph**, or call the Center for Device Regulation, Radiation Health, and Research at (02) 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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