Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 APR 2018

FDA ADVISORY
No. 2018-122

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS, ESTABLISHMENTS and GENERAL CONSUMING PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unregistered Medical Device (Unimex Nasal Oxygen Cannula (Pedia) with 7 Feet Crush Resistant Tubing)**

The Food and Drug Administration (FDA) hereby advises all concerned healthcare professionals, establishments and general consuming public against the purchase and use of **UNIMEX NASAL OXYGEN CANNULA (PEDIA) WITH 7 FEET CRUSH RESISTANT TUBING** whose picture appears below:

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device product has not gone through the registration process of the agency and

has not been issued with proper authorization in the form of Certificate of Product Registration. Pursuant to the provisions of 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 any health product that is adulterated, unregistered or misbranded are prohibited.**

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

In this regard, the public is hereby advised not to purchase the above-mentioned violative product and to be vigilant against the medical device products that are not registered with the FDA.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said medical device product.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that the 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 devices, utilize our online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**, or email us via **report@fda.gov.ph**, or call us at the Center for Device Regulation, Radiation Health and Research hotline 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

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FDA Director General

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