



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. 2023-0207-A

05 JUL 2023

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Lifting of the FDA Advisory No. 2023-0207 entitled "Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product ICARE® NEBULIZER KIT WITH PEDIATRIC AEROSOL MASK (NM06-002, 12ML)"

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, iCare® Nebulizer Kit with Pediatric Aerosol Mask (NM06-002, 12mL) has been notified by the Market Authorization Holder (MAH), Aviton Enterprises, in accordance to existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2023-0207 dated 06 February 2023 is hereby lifted.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to existing laws, rules, and regulations.

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) 8857-1900 loc. 8301.

To report any sale or distribution of unnotified medical device, contact the online reporting facility, **eReport**, through e-mail at ereport@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.


DR. SAMUEL A. ZACATE
Director General

DTN: 20221219132341

