Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No: 2022-1576

06 SEP 2022

TO: **ALL MEDICAL DEVICE MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED STAKEHOLDERS**

SUBJECT: **TRANSFER OF PRODUCT REGISTRATION OF ALCOHOL SWAB FROM CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH (CDRRHR) TO CENTER FOR DRUG REGULATION RESEARCH (CDRR)**

Alcohol swab with 70% isopropyl alcohol with intended use as antiseptic is a borderline product between a drug and a medical device. Alcohol products with minimum concentration of 70% isopropyl alcohol are within the jurisdiction of the Center for Drug Regulation and Research (CDRR) under Household Remedy Products.

On 23 January 2020, the Food and Drug Administration (FDA) issued FDA Circular No. 2020-001 entitled "Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements" delisting alcohol swab as registrable medical device.

In view of the above, the FDA hereby informs all medical device manufacturers, traders, distributors and other concerned stakeholders regarding the **transfer of product registration of alcohol swab with 70% isopropyl alcohol from the Center for Device Regulation, Radiation Health and Research (CDRRHR) to CDRR.**

To ensure the stability of supply of the said product in the market, an exhaustion period of one (1) year shall be given to the company. All existing Certificate of Product Registration (CPR) issued by the CDRRHR with expiration prior to 05 July 2022, shall be extended until 05 July 2023.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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