Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-2000

21 DEC 2022

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

SUBJECT: **Reiteration of the End of Transitory Period for Issued Provisional Authorizations under FDA Circular (FC) No. 2021-004 Concerning Rubbing Alcohol Products Following FC No. 2022-001**

On 06 May 2022, following the publication of FDA Circular (FC) No. 2022-001 in *The Manila Times* on 21 April 2022, the Food and Drug Administration (FDA) effectively repealed the interim guidelines provided under FC No. 2021-004, returned the jurisdiction over rubbing alcohol products to the Center for Drug Regulation and Research (CDRR) in light of the stability in supply of these products, and provided for the transitory period until 31 December 2022 within which affected stakeholders may comply with the applicable guidelines for securing the appropriate authorizations.

Thus, in order to ensure full dissemination and facilitate compliance to FC No. 2022-001, the FDA published regular reminders to concerned stakeholders through issuance of FDA Advisory Nos. 2022-1090 and 2022-1622 on 24 May 2022 and 19 September 2022, respectively.

In view of the foregoing, and as the current transitory period draws to an end, the FDA wishes to provide further reiteration and clarity on specific provisions of FC No. 2022-001:

1. **Issued provisional authorizations, such as License to Operate (LTO), Certificate of Product Notification (CPN) and previously-granted additional product lines for rubbing alcohol products with concentrations of 70% alcohol and beyond, will automatically be considered invalid beyond 31 December 2022. Thus, affected products are expected to be removed at the retailer level and voluntary recall of these products shall be performed by the said date.**
2. **Establishments with previously-issued provisional authorization that intend to continue to manufacture and/or distribute alcohol-based products under CCHUHSRR shall secure appropriate LTO and CPN, provided that prior reformulation and product classification have been conducted to ensure that the composition, intended use, claims and type of the product is within the scope of a cosmetic product.**
    a. Alcohol-based solutions must clearly indicate their product type and intended use as a cosmetic product in the filed notification. Relatively, CCHUHSRR may request for the submission of labeling to verify the intended use of the product.

b. "Virucidal" and "fungicidal" action are unacceptable claims for cosmetics. Additionally, hand sanitizers with primary claims "antiseptic" and/or "anti-bacterial" are unallowable.
c. For more information, manufacturers, traders, distributors and other concerned stakeholders are advised to refer to the Appendix III - ASEAN Cosmetic Claim Guideline of the ASEAN Cosmetic Directive for the guidance on allowable and prohibited claims.

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

DTN 20221209191508