Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2022-001

31 MAR 2022

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

SUBJECT: **Repealing FDA Circular No. 2021-004 "Revised Interim Guidelines for the Issuance of License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers, Distributors and Traders of Rubbing Alcohol Products Under the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research" dated 09 February 2021**

I. BACKGROUND

Through FDA Circular (FC) No. 2021-004, the Food and Drug Administration (FDA) issued the interim guidelines for the issuance of License to Operate (LTO) and Certificate of Product Notification (CPN) for manufacturers, distributors and traders of all ethanol and isopropanol products regardless of percent concentrations intended to be used as sanitizing, antibacterial and antiseptic agents under the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) to facilitate and streamline the process for the approval of these health products in order to sustain and meet the increased demand during the public health emergency.

Based on the Center's database, the number of notified rubbing alcohol and alcohol-based hand sanitizer products dramatically increased during the implementation of the Interim Guideline, and now, consumers and healthcare personnel are no longer having difficulty obtaining these products.

With stable supply of rubbing alcohol and alcohol-based products, the FDA determined and deemed it is appropriate to repeal the interim guidelines and provide the manufacturers, distributors and traders an exhaustion period for products covered by the interim guidelines.

The FDA commends all manufacturers, distributors and traders' contribution and initiative in providing the general public and health care professionals with ample supply of rubbing alcohols and alcohol-based hand sanitizer products in light of the increased demand during the surge of COVID-19 pandemic.

II. OBJECTIVE

This Circular aims to:

A. Repeal the interim guidelines provided under FC No. 2021-004;
B. Return the jurisdiction over rubbing alcohol products with concentrations of 70% and beyond to the Center for Drug Regulation and Research (CDRR); and,
C. Reiterate the applicable guidelines for securing authorizations for alcohol products under CDRR and CCHUHSRR.

III. SCOPE

This Circular shall apply to all establishments issued with provisional authorizations such as LTO and CPN as manufacturer, distributors and traders of rubbing alcohol products with concentrations of 70% and beyond covered by the interim guidelines. Manufacturers, distributors and traders of rubbing alcohol products with concentrations of less than 70% shall remain under the jurisdiction of the CCHUHSRR.

IV. GUIDELINES

A. The CCHUHSRR shall no longer accommodate applications for provisional authorizations such as LTO and CPN for manufacturers, distributors and traders of rubbing alcohol products with concentrations of 70% and beyond starting 1 July 2022.

   For establishments that plan to continue to manufacture and distribute rubbing alcohol products with concentrations of 70% and beyond after this date, the corresponding application of LTO and Certificate of Product Registration (CPR) for these types of products shall, hence, be lodged under CDRR. Particularly for the initial application of rubbing alcohol products with concentrations of 70% and beyond, the CDRR shall start receiving applications on 1 July 2022.

   Market authorization holders (MAH) and prospective applicants are hereby directed to refer to the FDA Citizen's Charter available on the FDA website and the following issuances to secure the appropriate authorizations:

   1. Securing an LTO
      - Department of Health (DOH) Administrative Order (AO) No. 2020-0017, entitled, "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003"
   2. Securing a CPR for Drug Products (Household Remedies)
      - AO No. 67 s. 1989, entitled, "Revised Rules and Regulations on Registration of Pharmaceutical Products"
      - Bureau Circular No. 5 s. 1997, entitled, "Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products"
      - AO No. 117 s. 1992, "Providing for the Classification of Household Remedies"
   3. Securing a CPN for Cosmetic Products

- FDA Memorandum Circular (FMC) No. 2015-010, entitled, "Guidelines on Issuance of Center for Cosmetics Regulation and Research User Account to Access E-Portal"
- FMC No. 2015-011, entitled, "Guidelines for Electronic Notification of Cosmetic Products (Cosmetic E-Notification Version 2.0) Using the FDA E-Portal"

B. Issued provisional authorizations, such as LTO, CPN and previously-granted additional product lines under FC No. 2021-004, shall be recognized as valid only until 31 December 2022. After this period, all previously-issued provisional authorizations through FC No 2021-004 shall be deemed invalid. No extensions, including product exhaustion, shall be accommodated after this period.

C. Establishments with existing and valid LTO as cosmetic manufacturers that have pending applications for additional product lines under the interim guidelines to produce rubbing alcohol products with concentrations of 70% and beyond, shall be automatically denied.

D. Establishments that will cease the manufacture and distribution of rubbing alcohol products with concentrations of 70% and beyond before the end of 31 December 2022 shall notify the FDA of the voluntary cancellation of the CPN following FDA Memorandum Circular No. 2015-011. The following shall be submitted:
   1. Letter of Intent for Voluntary Cancellation of LTO and CPN
   2. Two (2) Original Copies of LTO
   3. Copy of Inventory and Distribution Records

V. PENALTY CLAUSE

Applicable sanctions or regulatory actions shall be imposed upon those found in violation of the provisions of this Circular.

VI. SEPARABILITY CLAUSE

The provisions of this Memorandum are hereby declared separable and in the event of any such provision/s is/are declared invalid or unenforceable, the validity of enforceability of the remaining portions or provisions which are not affected, shall remain in full force and in effect.

VII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines Office of the National Register.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

DTN 20211202160847