



FDA CIRCULAR  
No. 2021-004

09 FEB 2021

**SUBJECT : 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**

## I. RATIONALE

In the exigency of service and in response to the current pandemic state of the country due to the COVID-19, the Food and Drug Administration (FDA) is hereby issuing the revised interim guidelines for the issuance of the 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. Accordingly, the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) is hereby tasked to facilitate and streamline the process for the approval of these health products which was previously lodged with the Center for Drug Regulation and Research (CDRR).

## II. OBJECTIVES

This Circular is being issued to provide FDA's interim regulatory guidelines to all manufacturers, distributors and traders seeking to produce rubbing alcohol for the issuance of a license to operate (LTO) and certificate of product notification (CPN), to ensure the safety and quality of these products and to aid in the supply sustainability due to the demand brought about by the continuing threat of infection due to COVID-19.

## III. SCOPE

This issuance shall apply to establishments seeking to manufacture, distribute and trade rubbing alcohol, regardless of strength, in the Philippines.

## IV. GUIDELINES

### 1. Application for a License to Operate

#### 1.1 Filing of Applications



1.1.1 Applications for the issuance of LTO as Cosmetic Manufacturer, Distributor or Trader shall be submitted through the FDA e-Portal System as prescribed in the FDA Circular No. 2016-004 entitled, "Procedure on the Use of the New Application Form for License to Operate (LTO) thru the Food and Drug Administration (FDA) Electronic Portal (e-Portal)"

1.1.2 All applications shall be deemed filed upon payment of required fees and charges.

1.2 Documentary Requirements for Issuance of License to Operate as per 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" and additional requirement, to wit:

1.2.1 Proof of capability to manufacture rubbing alcohol products  
(For licensed Cosmetic Manufacturer only)

### 1.3 Evaluation

The evaluation of all applications for LTO as Cosmetic Manufacturer, Distributor and Trader shall be based on satisfactory compliance to the applicable requirements or appropriate standards.

### 1.4 Inspection (For Manufacturers only)

1.4.1 Applicant establishments shall undergo Field Regulation Operations Office (FROO) inspection prior to the issuance of initial LTO.

1.4.2 During inspection, the establishment will be required to present the following documents, as may be applicable:

1.4.2.1 Standard Operating Procedures (SOPs),

1.4.2.2 Quality Assurance / Quality Control Documents,

1.4.2.3 Documents relating to the manufacture of the product

1.4.2.4 Documents relating to the distribution of the product Contract Agreements, if applicable

1.4.2.5 Product Line indicating capability to produce rubbing alcohol

### 1.5 Decision on Application

1.5.1 The appropriate authorization shall be issued to the applicant establishment which satisfactorily complied with all applicable requirements and standards.

1.5.2 The application shall be disapproved if upon evaluation, it was found that the applicant establishment has failed to satisfactorily meet the applicable requirements and standards.

1.5.3 Applications with incomplete requirements shall automatically be disapproved and requests for reconsideration shall not be entertained

1.5.4 The disapproval of an application is without prejudice to re-application. However, disapproval of application shall mean outright forfeiture of payment.

## 2. Application for a Certificate of Product Notification

### 2.1 Filing of Application for Notification of Rubbing Alcohol

- 2.1.1 All applications shall be submitted electronically via the FDA e-portal system.
- 2.1.2 To request for a user account for the notification application, follow the steps provided under FMC 2015-010.
- 2.1.3 Process for notification of rubbing alcohol shall follow the procedures under FMC 2015-011.

### 2.2 Guidelines and Requirements for the Application of Certificate of Product Notification (CPN) for Rubbing Alcohols

- 2.2.1 Rubbing alcohol shall be notified per formulation regardless of the different types of packaging used.
- 2.2.2 Rubbing alcohol having the same base formulation but different fragrance or colorant shall be notified as variant.
- 2.2.3 Rubbing alcohol's acceptable claims are only sanitizing or antibacterial and/or antiseptic. Application beyond these claims shall be disapproved.
- 2.2.4 Only Ethyl or Isopropyl Alcohol is acceptable ingredients responsible for sanitizing or antibacterial and/or antiseptic.
- 2.2.5 The following are the requirements for CPN application:

2.2.5.1 Declaration and Oath of Undertaking

2.2.5.2 Accomplished Online Application Form

2.2.5.3 Manufacturing/Distribution Agreement between Manufacturer, Trader or Distributor shall be submitted via email at [crraseannotation@fda.gov.ph](mailto:crraseannotation@fda.gov.ph) indicating the application case number in the email subject.

2.2.5.4 Duly-signed Certificate of Analysis (COA) of the Finished Product in English language (in pdf format) including Test for Methanol shall be submitted via email at [crraseannotation@fda.gov.ph](mailto:crraseannotation@fda.gov.ph) indicating the application case number in the email subject.

2.2.5.5 Complete labeling materials in Filipino or English language (in .png format) submitted via email at [crraseannotation@fda.gov.ph](mailto:crraseannotation@fda.gov.ph) indicating the application case number in the email subject. It shall follow the labelling guidelines under the ASEAN Cosmetic Directive (ACD) on labelling. Ethyl or Isopropyl Alcohol in generic box or more prominently displayed (implied/highlighted) shall not be allowed.

2.2.5.5.1 For products that are previously registered as household remedies under the CDRR, it shall follow the existing labelling guidelines provided under CDRR on drug products.

2.2.6 Any change of information in the product notification shall constitute a new notification application.

### **3. Validity of Authorizations**

A provisional LTO as Cosmetic Manufacturer, Distributor or Trader shall be issued and shall have a validity of one (1) year from the date of issuance. The validity of notification shall likewise follow the provisions for the LTO validity.

### **4. Postmarketing Surveillance of Rubbing Alcohol Products**

- 4.1 Rubbing alcohol products shall be subject to postmarketing surveillance activities of FDA.
- 4.2 A Product Information File (PIF) shall be prepared and kept by the company following the format as specified in FDA Circular 2018-001 or its future amendments.
- 4.3 Commercial product/s reflecting complete labeling information shall be submitted within two (2) months after receipt of acknowledged notification.

### **5. Fees and charges**

Applications shall be charged with the fees pursuant to the schedule of fees stated in AO 50 s. 2001, or its future amendments.

## **V. PENALTY CLAUSE**

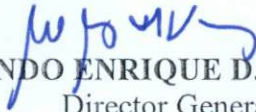
Applicable sanctions or regulatory tools shall be implemented following the Rules of Administrative Procedure provided in the IRR of RA 9711.

## **VI. REPEALING CLAUSE**

FDA Memorandum Circular No. 2020-001 and its amendments are hereby repealed.

## **VII. EFFECTIVITY**

This Circular shall take effect immediately after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the Office of the National Administrative Register of the UP Law Center, unless otherwise revoked or rescinded.

  
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