



19 MAR 2020

FDA MEMORANDUM CIRCULAR

No. 2020-001

SUBJECT : Interim Guidelines for the Issuance of Provisional License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers of Rubbing Alcohol Products Under the Center for Cosmetics Regulation and Research

I. BACKGROUND

In the exigency of service and in response to the declaration of the community quarantine due to the COVID-19, the FDA is hereby issuing interim guidelines for the issuance of authorizations for all ethanol and isopropanol products regardless of percent concentrations intended to be used as sanitizing, antibacterial and antiseptic agents. Accordingly, the Center for Cosmetic Regulation and Research (CCRR) 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 Memorandum is being issued to provide FDA's interim regulatory guidelines to all manufacturers seeking to temporarily produce rubbing alcohol, in light of the current increase in demand due to the COVID-19 pandemic, for the issuance of a license to operate (LTO) and certificate of product notification (CPN).

III. SCOPE

This issuance shall apply to establishments seeking to temporarily manufacture and distribute rubbing alcohol, regardless of the 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 shall be submitted through the FDA e-Portal System.
- 1.1.2 Applicant establishments shall follow the licensing procedure as prescribed in the following issuances:



1.1.2.1 Administrative Order No. 2016-0003 “Guidelines on the Licensing Requirements and Procedures of the Food and Drug Administration

1.1.2.2 FDA Circular No. 2016-004 “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)

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

1.2 Documentary Requirements for Issuance of LTO

The following are the documentary requirements for the issuance of LTO, applied as initial, for renewal or with variation:

1.2.1 Accomplished Application Form and Declaration and Oath of Undertaking

1.2.2 Proof of Business Name Registration

1.2.2.1 For Single Proprietorship – copy of Certificate of Business Registration issued by the Department of Trade and Industry (DTI);

1.2.2.2 For Corporation, partnership and other juridical person – Certificate of Registration issued by the SEC and Articles of Incorporation; or

1.2.2.3 For Cooperative – Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation

1.2.3 Site Master File (SMF)

1.2.4 Proof of Payment

1.3 Evaluation

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

1.4 Inspection

- 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
 - 1.4.2.5 Contract Agreements, if applicable

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 for Notification of Rubbing Alcohol.

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. In case fermentation is part of the manufacturing process of ethanol, care must be given to reduce natural methanol level as low as reasonably achievable.

2.2.4. The following are the requirements for notification application:

2.2.4.1. Declaration and Oath of Undertaking

2.2.4.2. Accomplished Online Application Form

2.2.4.3. Certificate of Analysis of the Finished Product including methanol concentration

2.2.4.4. Complete labeling materials in Filipino or English language (in .png format).

2.2.4.4.1. For products already notified as cosmetic products, it shall follow the labelling guidelines under the ASEAN Cosmetic Directive (ACD) on labelling.

2.2.4.4.2. 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.

2.2.4.4.3. For products that contains 80% ethyl alcohol or 75% isopropyl alcohol, please refer to Annex A.

Note: The Certificate of Analysis (COA) and sample Labeling Material shall be submitted separately via email at crraseannotation@fda.gov.ph. Indicate the application case number in the email subject.

2.2.5. A Product Information File (PIF) shall be prepared and kept by the company following the format as specified in FDA Circular 2018-001 upon receipt of the acknowledged notification. Upon audit, a complete PIF shall be made readily available and easily accessible by the Authorities. The PIF shall be retained for a minimum of three (3) years after the product is last placed in the market.

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 shall be issued and shall have a default validity of one (1) year from the date of issuance. However, for the purpose of this issuance, the provisional LTO shall be effective and valid for three (3) months only, which can be extended accordingly. The validity of notification shall likewise follow the provisions for LTO validity.

4. Postmarketing Surveillance of Rubbing Alcohol Products

Rubbing alcohol products shall be subject to postmarketing surveillance activities of FDA. Applicable regulatory tools shall be implemented to non-compliant and violative products.

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.



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