Note: This draft is only intended as a copy for comments during the stakeholder consultation period of the proposed guidelines. The content of this draft may change and does not prejudge any policy nor decision of the FDA. Citation of any text in this draft, for purposes other than the submission of comments as indicated in the issued announcement, is not recommended.

FDA CIRCULAR
No. _____

SUBJECT : Guidelines on the Filing and Submission of Applications for the Licensing of Cosmetic Establishments through the Food and Drug Administration (FDA) eServices Portal System

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I. RATIONALE

In pursuit of the principles under Republic Act No. 8792, otherwise known as the "Electronic Commerce Act of 2000", and Republic Act No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018", national government agencies transitioned into operating electronic systems to promote efficient delivery of government services. In the Food and Drug Administration (FDA), digitalization efforts were initiated beginning in 2013 through the establishment of an electronic application system for cosmetic product notification, followed later on by the online systems for the notification/registration of household/urban hazardous substances, toys and childcare articles, food products, and medical devices, and the licensing of health product establishments.

During the course of the digitalization of FDA licensing and registration services, several systems were gradually built. More recently, regulatory services of the FDA are moving towards a single platform, namely, the FDA eServices Portal System. This platform is envisioned to be a user-friendly and simpler platform to file and submit applications, intended to reduce inefficiency and redundancy presented by multiple application systems. This is also in line with the initiatives embodied in the Department of Health (DOH) Administrative Order 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" in the streamlining and harmonization efforts of government transactions and procedures. Through this Circular, the FDA eServices Portal is hereby updated to include License to Operate (LTO) applications of cosmetic establishments.

II. OBJECTIVE

This Circular aims to provide the procedural guidelines for the filing and submission of LTO applications of cosmetic establishments through the FDA eServices Portal System

III. SCOPE

This Circular shall cover the following LTO applications:

A. Types of Establishments

1. Cosmetic Manufacturer
    a. Cosmetic Manufacturer / Toll Manufacturer
    b. Cosmetic Manufacturer-Packer / Toll Packer
    c. Cosmetic Manufacturer-Repacker / Toll Repacker

2. Cosmetic Distributor
    a. Cosmetic Distributor-Importer
    b. Cosmetic Distributor-Exporter
    c. Cosmetic Distributor-Wholesaler

3. Cosmetic Trader

B. Types of LTO Applications

1. Initial
2. Renewal
3. Variation

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the same definition as prescribed in Republic Act No. 9711 and its Implementing Rules and Regulations (IRR), DOH Administrative Order (AO) No. 2020-0017, FDA Circular No. 2013-002, their amendments, and other applicable laws and regulations

V. GUIDELINES

A. The procedural guidelines on the filing and submission of an FDA eServices LTO application for establishments enumerated under Section III of this FDA Circular shall be expounded herein. Whereas, the technical requirements and guidelines relative to the licensing and inspection of cosmetic establishments are provided in DOH AO No. 2020-0017, FDA Circular Nos. 2013-002 and 2013-002-A.

B. By applying for an FDA LTO, the establishment understands and abides by the rules and regulations set forth by the Agency. The establishment shall have the ultimate responsibility in ensuring compliance with applicable national and/or international standards of safety, quality, purity, and efficacy developed and/or adopted by the FDA for cosmetic products which are manufactured, imported, exported, distributed, sold, offered for sale, promoted, and/or advertised under the authorization granted through their LTO and other marketing authorizations issued by the FDA.

C. **Application Process.** The applicant shall follow the updated procedure, as provided in this Circular, in the submission and filing of applications, amending the procedure originally prescribed under FDA Circular No. 2016-004. Applications shall be in accordance with the following guidelines:

1. **Application Requirements and Procedure.** The application requirements and procedure are specified in the following Annexes of this Circular:

   a. Annex A – LTO Requirements for Cosmetic Establishments
   b. Annex B – Procedure in the Submission of an Initial LTO Application
   c. Annex C – Procedure in the Submission of a Renewal LTO Application
   d. Annex D – Procedure in the Submission of a Variation Application
   e. Annex E – Procedure for Checking the Status of an Application
   f. Annex F – Procedure Voluntary Cancellation of an Application

2. **Filing of an Application**

   a. **Accessibility of the FDA eServices Portal System.** Applications shall be filed online through the FDA eServices Portal System website (https://eservices.fda.gov.ph). A valid official e-mail address is required to file and submit an application.

   b. **Declaration and Undertaking Upon Submission of the Application.** Agreement to the "Declaration and Undertaking" is required in order to proceed with the application. Such conveys a binding agreement of the applicant company with the FDA to provide true and accurate information in support of the application, to affirm the primary responsibility of the LTO holder over the cosmetic products, and to undertake compliance with all applicable FDA standards, rules and regulations contingent with their authorization, including full cooperation with FDA licensing, inspection, and post-marketing surveillance activities.

      Any misrepresentation of the information in this application shall be subjected to administrative and criminal liabilities, provided by Republic Act No. 9711, which includes, but are not limited to disapproval of application, suspension, cancellation, or revocation of the LTO.

   c. **Security of the Declared E-mail Address.** All transactions with the FDA shall be communicated to the applicant company though the declared e-mail address during the application.

      The applicant company shall bear the responsibility of ensuring the accessibility, security and integrity of such e-mail address to their respective Authorized Person/s, Qualified Personnel, and/or owner of the establishment. Only the official e-mail address shall be used for application purposes. All other e-mail addresses shall not be allowed. The FDA shall not be held liable or responsible in any way for the loss and/or any compromise of access to the declared e-mail address.

      In the event that the applicant company wishes to change the declared e-mail address during the initial application, the applicant may send a request addressed to the FDA – Food and Drug Action Center at fdac.pacd@fda.gov.ph.

d. **Quality of Declared Information and Uploaded Documents**

i. In filling-up the fields in the electronic application (e-Application) form, the applicant shall ensure that the declared information is consistent with the uploaded supporting documents, such as the name and address of the establishment, name of owner, among others.

ii. Documents required to be uploaded, in support of the e-Application, shall be in accordance with the following specifications:
   1. Portable document file (PDF) format; and,
   2. Maximum of 2 megabytes (MB) file size.

iii. Once the e-Application Form is completed, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the terms and conditions, the applicant confirms to the correctness of information provided and data privacy terms.

iv. The application summary shall be automatically sent to the applicant's valid e-mail address to indicate the successful submission of the application in the eServices Portal. Upon submission, the information declared in the e-Application is considered final.

e. **Timing and submission of applications**

i. Applications are processed one at a time, such that renewal applications and each variation application must be filed separately. No application for variation of LTO shall be made and granted when an establishment has a pending application for renewal of LTO, or vice versa.

ii. An applicant may only file for a renewal application of an LTO within three (3) months prior its expiry. Applications filed after the validity date of the LTO shall be subject to a surcharge as prescribed in RA No. 9711 and its IRR.

iii. Applications shall be accepted in accordance with the existing guidelines on the schedule of receiving. Further, applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.

f. **Monitoring of the Status of Applications.** The status of the filed application can be monitored by the applicant through the FDA eServices Portal System. A reference code will be sent to the registered e-mail address specified in used for the e-Application to validate the request to view the status.

Further, the applicant shall have a period of 3 calendar days within which to acknowledge receipt of any communication from the FDA pursuant to these Guidelines, otherwise it is deemed received

g. **Voluntary Cancellation of Application.** The application may be cancelled by the applicant voluntarily stating the reason for cancellation through the FDA eServices Portal System. A reference code will be sent to the registered e-mail address specified in used for the e-Application to validate the request for cancellation.

Applications cancelled during the evaluation stage or after the payment has been made shall mean the outright forfeiture of the payment. Resubmission of applications thereafter shall subject to new fees.

3. **Pre-assessment.** All cosmetic licensing applications shall undergo the pre-assessment step, following Republic Act No. 11032, which covers the determination of the completeness of information and documents submitted. The pre-assessment of applications shall be guided by the following.

a. The pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.

b. Applications with incomplete data entries and document submissions shall not be accepted and the application will not proceed to the next step of the process.

c. The FDA shall inform the applicant through the registered email address of the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. However, if the application did not pass the pre-assessment step, the FDA shall notify the applicant reason/s for non-acceptance e.g., deficiency/ies found and prompt the applicant to file a new application.

d. A successfully pre-assessed application is not equivalent to an approved application. The evaluation of the correctness and sufficiency of the submitted documentary requirements with reference to existing administrative and technical standards, rules, and regulations shall be conducted only during the evaluation and inspection steps as determined by the FDA.

4. **Payment of Fees.** The procedure for the payment of fees and charges shall be as follows. Any updates, changes and/or additions to the existing FDA payment channel shall be announced through separate issuances.

a. Payment of prescribed fees as indicated in the Order of Payment shall be done through the following available payment channels based on existing FDA issuances:

i. Over-the Counter at the Landbank of the Philippines (LBP) using the LBP Oncoll Payment Slip based on FDA Memorandum Circular No. 2013-046 through this link, https://bit.ly/36ChH4X

The Oncoll Payment Slip shall reflect the following information:

1. Account Number (per category of the product/center)
2. Reference No. 1 – Account Code (reflected in the Order of Payment)
3. Reference No. 2 – Company Name
4. Merchant Name – Food and Drug Administration

ii. Online through:

1. LBP Online Payment Link.Biz Portal based on FDA Advisory No. 2021-0246 (https://bit.ly/3DmdPRv)
2. BANCNET online (https://bit.ly/3uB8PEL)

Online payments should indicate the reference number reflected in the Order of Payment.

b. Once payment has been made, LBP or Bancnet will process the payment and send a transaction report to FDA which usually takes a minimum of two (2) working days. Upon receipt of the report, the Cashier Section of the FDA shall check the details, confirm if the payment has been made in full, and posts the payment in the FDA eServices Portal System. Posting of payment may take a two to five (2-5) working days in accordance to Citizen's Charter depending on the volume of paid applications received.

c. Applicants will receive a system-generated message through the registered e-mail address on the status of the payment made once posted or if there is a need to further settle the remaining balance. An Acknowledgment Receipt will be issued if a full payment has been made. Otherwise, a notification on payment deficiency will be issued in cases of incomplete payments.

d. Applications with complete documentary requirements and payment shall receive an Acknowledgement Receipt from FDA, containing the number or code of the FDA employee who received the application, the reference number, agency logo, the date and time of application, payment, and the statement of completeness of the documents submitted. An application is considered filed once the applicant receives the Acknowledgement Receipt.

5. **Evaluation of the Application.** A filed application will undergo evaluation of the correctness and sufficiency of the submitted documentary requirements with reference to existing administrative and technical standards, rules, and regulations. Inspection will be conducted as determined by the FDA, in accordance with the guidelines under DOH AO No. 2020-0017, FDA Circular Nos. 2013-002 and 2013-002-A, and their future amendments.

An approval of the application shall be based on the satisfactory compliance to the administrative and technical requirements reviewed during evaluation and, if applicable, inspection.

6. **Grounds for Disapproval.** The grounds for disapproval of LTO application may be any of the following, as provided in DOH AO No. 2020-0017:

   a. The documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;
   b. Absence of physical office upon inspection, without permission or approval from FDA;
   c. The applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law or appropriate standards;
   d. The owner has violated any of the terms and conditions of its license; and,
   e. Such other analogous grounds or causes as determined by the FDA.

   The disapproval of an application is without prejudice to re-application; provided that the deficiencies listed in the Letter of Disapproval (LOD) have been addressed before submitting a new application. As the disapproval of the application means the outright forfeiture of the payment made, re-submitted applications shall be subject to new fees.

7. **Releasing of the Results of the Application**

   a. If the application is approved, the FDA shall send the LTO for initial and renewal applications or the updated LTO for variation applications to the registered e-mail address of the applicant. The LTO may also be accessed through the FDA eServices Portal System.

      Issued LTOs processed filed through this FDA Circular under the FDA eServices Portal System shall be provided an updated LTO number in the following format:
      Old: **300000XXXXX**
      New: **CCHUHSRR-(Region)- Cosmetic- (Activity)- (Sequence Number)**

      Upon receipt of the LTO, the establishment shall print the LTO on a standard A4 size (21 cm x 29.7 cm) paper, on full-colored page and in portrait orientation. It shall be positioned in the most conspicuous place within the business establishments.

   b. If the application is disapproved, the FDA shall inform the applicant through its registered e-mail address of the reason for such action on the application.

VI. SEPARABILITY CLAUSE

The provisions of this FDA Circular 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. TRANSITORY PROVISIONS

All applications shall be filed online through the eServices Portal System upon the effectivity of this Circular. Applications filed through the FDA ePortal System prior the effectivity of this Circular shall be processed in accordance with DOH AO No. 2020-0017, FDA Circular No. 2016-004, and other applicable guidelines. Establishments with a valid LTO issued via FDA ePortal System shall be honored for the duration of its validity.

VIII. REPEALING CLAUSE

This Circular hereby repeals FDA Circular 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)". Other related issuances inconsistent or contrary to the provisions of this Circular are hereby amended or modified accordingly.

IX. EFFECTIVITY

This FDA Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing with the University of the Philippines – Office of the National Administrative Register (UP-ONAR). The provisions stipulated in this FDA Circular shall remain in effect unless otherwise revoked or repealed.

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Director General