Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Amendment to 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"**

I. RATIONALE

Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" mandates the FDA to establish and maintain effective health regulatory system to promote safety, quality, and efficacy of health products. Pursuant with the aforementioned, the FDA, as the regulatory arm of the Department of Health (DOH) is mandated to issue standards and appropriate authorizations that cover establishments, facilities, and health products under its jurisdiction. Such endeavor shall be visible in its regulation of Manufacturers, Traders, and Distributors (Importers, Exporters, and Wholesalers), among others, engaged in business and operations involving health products prior to manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship activities.

In 2018, RA No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act" is issued which aids in the promotion of streamlined and simplified transactions in the government. Hence, the FDA, congruent with RA 11032, established a unified licensing guidelines to adopt a more harmonize licensing system across all health products under its jurisdiction through the issuance of Administrative Order (AO) No. 2020-0017 otherwise known as the "Revised Guidelines on the Unified Licensing Requirements and Procedures of the FDA Repealing AO No. 2016-0003"

Through the course of implementation of AO No. 2020-0017, there are various regulatory challenges in the context of documentary requirements and internal process amidst the increasing adoption of streamlined application system and further compliance with existing standards for inspection and post-marketing surveillance.

In the pursuit of achieving a harmonized regulatory system and aligning with the aforementioned policies, this Administrative Order is hereby issued.

II. OBJECTIVES

The objectives for issuing this Administrative Order are as follows:

1. To further reengineer and streamline the FDA's processes and automate its system for initial, renewal, and variation application for License to Operate (LTO) through the FDA eServices Portal System; and
2. To update the list of documentary requirements for pre-license application, in addition to other technical requirements that shall be presented during inspection of covered FDA regulated establishments.

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III. SPHERE OF APPLICATION

A. The following establishments, whether public or private, shall be covered by this Order:

1. Manufacturers, including Packers/Repackers, and Refurbishers of medical devices;
2. Cosmetic/HUHS Manufacturers/Refillers;
3. Traders;
4. Distributors as Importers, Exporters, and/or Wholesalers;
5. Food Business Operators;
6. Drug outlets, such as drugstores, pharmacies (community, or institutional); or *boticas,* and retail outlets for non-prescription drugs (RONPD);
7. Retailers of Medical Devices including groceries, convenience stores, and supermarkets; and
8. Clinical Research Organizations (CROs) and Sponsors

B. The scope of the health products shall include, but not be limited to:

1. Under the CCHUHSRR, all cosmetic products, household/urban hazardous substances (HUHS), including household/urban pesticides, and toys and childcare articles;
2. Under the CDRR, all drugs, including vaccines, biologics, veterinary medicines and animal health products, medical gases, traditional medicine, and herbal medicines;
3. Under the CDRRHR, all medical devices, radiation emitting devices, in-vitro diagnostic devices and reagents; refurbished medical devices; custom-made medical devices; equipment or devices used for treating sharps, pathological and infectious wastes, water treatment devices/systems; and other health-related devices as determined by the FDA; and
4. Under the CFRR, all processed food products, food supplements, raw materials, ingredients and additives for food.

This does not preclude the FDA from updating the scope of health products and establishments which requires regulation in accordance with the FDA rules and regulations.

C. The following shall NOT be covered by this Order:

1. Organizers of national and international trade fairs and exhibits;
2. Donors, organizations or persons involved in donations, medical missions and other humanitarian activities;
3. Manufacturers, Traders, or Distributors of collector's items;
4. Retailers of cosmetics and household/urban hazardous substances, including household/urban pesticides and toys and childcare articles;
5. Groceries, convenience stores and supermarkets of foods and cosmetics, slaughterhouses or abattoirs, dressing plants, fish ports, wet markets, supermarkets, school canteens, fast foods, restaurants, kiosks, caterers, chandlers, and the likes; and
6. Facilities covered by the DOH One Stop Shop Licensing System.

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D. The licensing of the following establishments or persons shall be governed by separate rules and regulations:

1. Salt Manufacturers and Distributors shall follow RA 8172 (ASIN Law) and its revised IRR;
2. Bottled Water Manufacturers shall follow AO No. 18-A s. 1993;
3. Radiation facilities;
4. Vapor product and heated tobacco product establishments shall follow DOH AO No. 2020-0055;
5. Operators of pest control for non-agricultural purposes shall follow DOH AO No. 2019-0010;
6. Applicators of household/urban pesticides and their training providers shall follow DOH AO No. 2019-0010; and
7. Other establishments that may not be covered under the scope and coverage such as applicability to medical devices, etc.

IV. DEFINITION OF TERMS

For the purpose of implementing this Order, the terms used shall have the meaning as defined in RA 9711, its IRR, and related laws and regulations. Further, the following terms are hereby defined for greater clarity:

A. **Authorized Person -** refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity.

B. **Contract Research Organization (CRO) –** refers to a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions (ICH GCP 1.20).

C. **Custom-Made Medical Device** – refers to any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. For the purpose of clarity, mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made medical devices.

D. **Distributor/Exporter -** refers to any establishment that exports raw materials, active ingredients and finished products for distribution to other establishments outside the country.

E. **Distributor/Importer** – refers to any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed establishments

F. **Distributor/Wholesaler -** refers to any establishment that procures raw materials, active ingredients and/or finished products from a local FDA-licensed establishments for local distribution on wholesale basis.

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G. **FDA Academy -** refers to an office under the Policy and Planning Service of the FDA that offers health regulatory webinar and technical training to external Stakeholders.

H. **Initial Application** or **Original Application -** refers to the LTO applied to FDA prior to engaging in the business or operation involving the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

I. **Major Variation** covers changes in the operations of the establishment that may affect significantly and/or directly the aspects of safety and quality and when applicable, efficacy of the products.

J. **Minor Variation** covers changes in administrative matters and/or changes in the operations of the establishments but with minimal impact on the safety, quality, and when applicable, the efficacy of the products.

K. **Manufacturer -** refers to any establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing, and labeling with the end in view of its storage, sale or distribution. Provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies.

L. **Repacker -** refers to any establishment that repacks a finished product into smaller quantities in a separate container and/or secondary packaging, including but not limited to relabeling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.

M. Packer – refers to any establishment that packages bulk product into its immediate container with the end view of storage, distribution, or sale of the product.

N. **Pre-licensing Inspection -** refers to an organized examination or formal evaluation of the facility(ies), warehouses, and/or offices of an establishment applying for an initial application or a major variation of its existing license.

O. **Qualified Person (QP)** refers to an organic or full-time employee of the establishment who possesses technical competence related to the establishment's activities and health products by virtue of his profession, training or experience. A qualified person has the responsibility to comply with the technical requirements of the FDA or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting inspection or Post-Marketing Surveillance (PMS) activities. The qualified person may also be the duly Authorized Person of the establishment.

P. **Renewal Application** refers to the LTO applied to FDA before the expiration of the validity of the current LTO for the business operation continuity involving manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

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Q. **Refurbished Medical Device -** refers to the medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it: a.) stripping into component parts or subassemblies; b.) checking their suitability for reuse; c.) replacement of components/sub-assemblies not suitable for reuse; d.) assembly of the reclaimed and/or replacement components/sub-assemblies; e.) testing of the assembled device against either original or revised release criteria; or f.) identifying an assembled medical device as a refurbished medical device. (ASEAN Medical Device Directive, 2015).

R. **Retailer -** refers to any establishment which sells or offers to sell any health product directly to the general public.

S. **Risk Management Plan** refers to a set of health product vigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to health products, and the assessment of effectiveness of those interventions. The risk management plan is a requirement for the issuance of the appropriate authorization.

T. **Routine Inspection** - refers to the usual process, which may be physical or remote, of the facility(ies), warehouses, and/or offices of an establishment, which is conducted by the FDA at any time during the validity of a license of an establishment.

U. **Site Master File -** refers to the specific information about the quality assurance, the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of an operation is carried out on the site, a Site Master File needs only describe those operations, e.g., analysis, packaging, for documentation.

V. **Special Permit –** refers to a form of authorization granted to entities that provide drugs to be used only for a specific purpose, such as but not limited to, either medical missions, employee or constituent vaccinations, or other health-related programs and are not for sale or resale. For other purposes, such as promotion, advertising, or sponsorship of drug product, a Sales Promotions Permit shall be secured in lieu of Special Permit.

W. **Sponsor -** refers to an individual, company, institution, organization or an entity which takes the responsibility for the initiation, management, and/or financing of a clinical trial.

X. **Trader** refers - to an establishment which is a registered owner of a health product and procures the raw materials and packing components and provides the production, monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed Manufacturer. In addition, a trader may also engage in distribution and/or marketing of its products.

Y. **Virtual Office** refers to an off-site business location where certain services of the establishments are provided.

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V. GENERAL GUIDELINES

A. All establishments, whether public or private entity, engaged in business or operation on health products shall first secure a License to Operate (LTO) issued by the FDA and, when applicable, product market authorizations, i.e., Certificate of Product Registration (CPR), Certificate of Product Notification (CPN), before engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship activities.

B. All establishments shall have at least one (1) Qualified Person. The QP, upon and during employment in the establishment, is not and shall not in any way be connected to, employed by or engaged with any other FDA-regulated establishments.

   A single Qualified Person may be allowed by the FDA to handle a single establishment with multiple FDA-licensed activities; Provided, that the QP remains to sufficiently carry out his/her duties and responsibilities as provided in this Order.

   The QP shall ensure good quality submissions, by following updated procedural guidelines, prescribed format and contents of administrative and technical documentary requirements, and through effective and efficient communications with the FDA pertaining to regulatory filings. Further, the QP shall ensure continuous compliance of his/her affiliated establishment to regulatory standards, rules, and regulations, and timely coordination in inspections and PMS activities.

C. The responsibility of ensuring the safety, efficacy, quality and/or purity of any health products identified under Section III of this Administrative Order which are sold in its original packaging (container) of which the seal has not been broken or tampered with shall rest upon the establishments involved in the supply chain for sale, handling, transport, distribution, trading and storage among others.

D. Establishments shall comply with the applicable standards, including but not limited to Good Manufacturing Practices (GMP), Good Laboratory Practices, Good Clinical Practices (GCP), Good Distribution and Storage Practices (GDSP), among others, in the conduct of their licensed activity(ies).

E. In case the health product has been banned or withdrawn for health and safety reasons in the country of origin, the importer shall immediately undertake the necessary measures in banning its sale, distribution, or donation, or its immediate recall, withdrawal or seizure from the market.

F. Establishments engaged in health products declared by FDA to be injurious, unsafe, or dangerous shall be required to immediately recall, withdraw, seize the product, or ban its sale, distribution, or donation to the public.

G. The establishment shall inform the FDA of any changes or variations made to its license and a corresponding application shall likewise be made for re-issuance of an LTO.

H. All licensed Manufacturers shall be granted an LTO based on the minimum requirements set by FDA in order to operate a manufacturing plant. A Certificate of GMP Compliance shall only be issued upon demonstration of satisfactory compliance with GMP standards and effective within the validity of the current LTO. Thereafter, the Certificate of GMP Compliance shall be issued each time the LTO is renewed.

I. Manufacturers and Distributors shall declare on their application the list of sources and name of products for each source (regardless whether finished/semi-finished/raw materials/active pharmaceutical ingredients/excipients).

J. All FDA-required information, education, and communication campaign materials shall be displayed in the establishment's conspicuous area.

K. For Drug establishments:

1. All drug or pharmaceutical establishments based on Section 31 of RA 10918 or the Philippine Pharmacy Act, whether public or private, shall be under the supervision of a registered pharmacist when operating or open for business, unless otherwise allowed by other pertinent laws or regulations.
2. All entities, whether government or non-government, that regularly procure drugs on wholesale basis from appropriate FDA-duly licensed drug establishments for distribution to their constituents shall be licensed as a drug distributor.
3. All drug distributors shall not sell directly to the general public or consumer, unless they have an LTO as drugstores.
4. All CROs, Sponsors and other concerned entities shall adhere to existing ethical and scientific quality standards of safety and efficacy in the conduct of clinical trials.
5. No CRO and Sponsor shall be involved in the conduct of clinical trials without a license from the FDA. Likewise, no CRO and Sponsor shall be involved in the conduct of clinical trials without a license from the FDA. Licensed CROs/Sponsors that import/export product subject for clinical trials are no longer required to secure a separate LTO.

L. For Cosmetic/HUHS establishments:

1. All establishments engaged in the compounding/mixing of Cosmetic/HUHS products shall secure an LTO as Cosmetic/HUHS Manufacturer.
2. All licensed Cosmetic/HUHS establishments with refilling activity shall only be applied as a Cosmetic/HUHS Manufacturer.
3. All Cosmetic/HUHS establishments applying for an initial application as a Manufacturer shall declare the refilling activity if applicable. On the other hand, all Cosmetic/HUHS Manufacturers with existing LTO shall apply a variation application to add refilling activity, if applicable.
4. Specific guidelines on the licensing and inspection of Cosmetic/HUHS Manufacturers/Refillers and establishments manufacturing customized cosmetics shall be issued through separate issuances.

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M. For Food Business Operators:

1. All establishments shall comply with the general principles of food hygiene including the provisions provided for by Presidential Decree No. 856 on the Code of Sanitation and other general requirements.
2. As appropriate, all Food Business Operators shall comply with the relevant standards and requirements of Hazard Analysis Critical Control Point (HACCP), Sanitary Standard Operating Procedures (SSOP), and other good practice regulation and guidelines expounded in Section V.5 of this AO, to ensure safety and quality of products.
3. LTO is a requirement before a food establishment can join food trade and exhibitions, conduct market research or testing of unregistered processed food products. CPR shall be required if the imported product is offered for sale or for "free tasting" during the food trade and exhibitions.
4. All establishments shall comply with food safety standards recognized by the Food and Agriculture Organization of the World Health Organization.

N. Attendance to trainings and seminars of the FDA Academy shall no longer be a requirement in the application for FDA LTO. Stakeholders may provide proof of training from other institutions offering technical courses relevant to their establishment and activity. Stakeholders may still avail of trainings and seminars offered by the FDA Academy as provided in separate issuances.

VI. SPECIFIC GUIDELINES

A. The requirements for applying for LTO shall be as follows:

1. Initial LTO

    a. Accomplished eApplication Form with Declaration of Undertaking;
    b. Proof of Business Name Registration;
    c. Proof of Capitalization for Manufacturers and Traders (Latest Audited Financial Statement with Balance Sheet or Declaration of Capitalization);
    d. Payment of Fees; and
    e. For Manufacturers: Site Master File, Risk Management Plan, and Floor Plan
    f. Self -assessment checklist
    g. Certificate of Compliance with technical requirements

2. Renewal of LTO

    a. Accomplished eApplication Form with Declaration of Undertaking; and
    b. Payment of Fees

3. Variation

    a. Accomplished eApplication Form with Declaration of Undertaking;
    b. Documentary requirements depending on the variation or circumstances of the establishment or the product as shown in Annex C of this Order; and
    c. Payment of Fees

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Note: The transfer of location of a manufacturing/packing/repacking plant is considered as major variation for Manufacturer/Packer/Repacker and shall be applied and paid as an Initial Application for LTO

4. For Manufacturers and for establishments applying for LTO or for major variations, as applicable, the following documents shall be presented to the FDA inspector for examination or review, ~~when required:~~

    a. **Risk Management Plan (RMP)** - which shall be required for Manufacturers, Traders, and Distributors (Importer, Exporter, and/or Wholesaler) of drugs, cosmetics, HUHS, including household/urban pesticides, and toys and childcare articles, and medical devices; and medium and large Food Manufacturers.
    b. **Site Master File (SMF)** - which shall be required for applicants applying for LTO as manufacturers of drugs, cosmetic, household/urban hazardous substances, including household/urban pesticides and toys and childcare articles, medical device manufacturers, and large and medium food manufacturers, among others.

All afore-mentioned Establishments shall ensure that the RMP and SMF documents are developed and readily available at all times.

Guidance for the above requirements is attached as Annex A.

B. The procedure for application for LTO shall be as follows:

1. Filing of Applications

    a. All establishments applying for initial, renewal, or variation shall submit their application through the FDA eServices Portal System as guided by the latest issuances.

        Applications lodged through the FDA eServices Portal System are a responsibility and accountability of the Owner/President/CEO of an establishment, as such only the duly authorized personnel of applicant-establishments and the e-mail address and its password shall be entrusted with such FDA applications. For purpose of emphasis, all consultants, liaison officers, or freelancers doing business with FDA or work on a per product registration/notification basis shall not be considered as duly authorized/qualified persons.

    b. Pre-assessment shall be conducted based on the submitted application and documentary requirements with regard to its completeness and correctness. Incomplete submission shall not be accepted and the application shall not proceed to the next step of the process.

        The submission of an application following a successful pre-assessment shall not guarantee an approved application. The evaluation of the submitted documentary requirements with reference to existing administrative and technical standards, rules, and regulations shall be conducted during the evaluation and inspection steps.

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c. For applications with complete and correct documentary requirements and posted payment, the FDA shall issue an Acknowledgement Receipt containing the name of the personnel who received the application, reference number, agency logo, the date and time of application, payment, and the statement of completeness of the documents submitted. An application shall be considered filed once the applicant receives the Acknowledgement Receipt.

d. All transactions with the FDA shall be communicated to the applicants using the registered e-mail address provided during the initial application. The applicant shall be responsible in making sure that the e-mail address is within the scope and access of the Authorized Person/s and/or Qualified Personnel of the establishment.

e. Application for renewal shall be done within three (3) months prior to the expiration of the validity date of the LTO. Applications filed after the validity date of the LTO shall be subject to surcharge as prescribed in RA 9711 and its IRR.

f. No application for variation of LTO shall be done and shall be granted when an establishment has a pending application for renewal of LTO, or vice versa.

g. The applicant shall receive the LTO in their registered e-mail address and may also be accessed through the FDA eServices Portal System. Upon receipt of the LTO, the establishments 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 placed on the most conspicuous place within the business establishments.

C. Payment

1. Payment of prescribed fees as indicated in the Order of Payment shall be done through the following payment channels, based on AO No. 50 series 2001 and its latest amendment, and other existing FDA issuances:

   a. Through Over-the Counter at LBP using the LBP Oncoll Payment Slip (to the Center's LBP Clearing Account, FDA Circular No. 2013-046
   b. Through Online LBP Link.Biz Portal
   c. Through Online Bills payment (Bancnet)

2. Application payment made including but not limited to the following shall not be accepted and posted in the system.
   a. Application payments with incomplete/insufficient amount paid.
   b. Application payments with Wrong reference number provided.
   c. Application payments made through a Wrong payment channel.

3. Additional payment channels shall be updated through a separate issuance.

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D. Evaluation

1. The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed;
2. Any of the following or similar instances shall be a ground for disapproval:
   a. The documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;
   b. The applicant made misrepresentations, false entries, or withhold any relevant data contrary to the provisions of the law or appropriate standards;
   c. The owner has violated any of the terms and conditions of its license; and
   d. Such other analogous grounds or causes as determined by the FDA.
3. Automatic renewal as provided for by the IRR of RA No. 11032, specifically Rule VIII. Section 1. *On When Shall Automatic Approval of an Original Application or Request be Granted*, shall apply; and
4. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.

E. Inspection

1. The conduct of pre-licensing inspection shall be mandatory for all Manufacturers, Distributors, and Traders of Food, Device, Cosmetic, and Drug products prior to the issuance of an LTO.
2. The FDA shall have the authority to enter any FDA-licensed establishments and establishments selling FDA-regulated health products during operating hours to conduct routine or spot check inspections.
3. A Certificate of Compliance with technical requirements shall be issued to establishment following a satisfactory submission of documentary requirements and compliance with technical obligations.
4. The FDA may conduct inspections in collaboration with the Local Government Units and other agencies or offices under the DOH, Department of Agriculture, and Department of Interior and Local Government or other enforcement agencies as deemed necessary based on RA 9711 and other applicable laws.
5. Establishments shall not be precluded from utilizing virtual offices for selected operations; Provided, that the establishment must have a physical site where the FDA-licensed activity takes place prior, during, and after the issuance of the FDA marketing authorizations. Correspondingly, it shall be the address of the physical site which shall be reflected in the FDA-issued LTO. The FDA shall not recognize a virtual office as the address to be reflected in all documentary requirements when transacting with the Agency.

   Covered establishments may utilize virtual offices and other online facilities, in cases permitted by the FDA, in addition to the maintenance of a physical site.

6. The guidelines outlining the parameters for inspection shall be issued through a separate issuance.

F. Checking of Application Status

The applicant shall check or view the status of the application through the FDA eServices Portal System. Personal visits shall be discouraged.

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G. Releasing of LTO

The FDA shall send the approved LTO to the registered e-mail address of the applicant and shall also be accessed through the FDA eServices Portal System.

H. The validity of LTOs and the applicable fees and other charges shall be covered by the latest FDA issuance.

I. An LTO shall be canceled through the following instances:

1. Automatic cancellation if the establishment failed to file an application for renewal after one-hundred twenty (120) days from the date of expiration;
2. Upon verification of the actual status of the establishment through inspection;
3. Imposed by the FDA as a penalty, if warranted; and
4. Voluntary filing through a formal notification with the FDA based on the following conditions:

    a. If the establishment voluntarily filed an LTO cancellation before its expiration, then decided to continue the business operation after closure of the establishment, the application shall be considered as "initial application" without surcharge;
    b. If the establishment voluntarily filed an LTO cancellation after its expiration, then decided to continue the business operation after closure of the establishment, surcharge shall be imposed. Computation of surcharge shall be based on existing FDA guidelines on fees and charges.

5. When the license is canceled either through an inspection verification or voluntarily, the FDA shall retain jurisdiction over violations committed by the establishments while it was in operation.

VII. PENALTY CLAUSE

Sanctions over violations of any of the provisions of this Administrative Order shall be based on the Rules of Administrative Procedure provided in the IRR of RA 9711.

VIII. TRANSITORY PROVISION

All existing applications for LTO deemed received prior the effectivity of this Order shall be processed according to previously approved issuances.

All establishments with valid LTO prior to the effectivity of this Order shall be given a period of one (1) year to comply with the provisions hereof.

IX. REPEALING CLAUSE

AO No. 2020-0017 entitled, "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No.

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2016-0003" is hereby repealed. Other issuances or part thereof, pertaining to specific guidelines for certain establishments which are found to be inconsistent with the provisions of this AO are hereby repealed accordingly.

X. SEPARABILITY CLAUSE

If any portion or provision of this Order is declared invalid or unenforceable or unconstitutional, the validity or enforceability of the remaining portions or provisions shall not be affected, and this Order shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional portion or provision.

XI. EFFECTIVITY

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

DR. MARIA ROSARIO S. VERGEIRE, MPH, CESO II
Officer-in-Charge, Secretary of Health

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