Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Prescribing the Rules, Requirements and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017**

I. RATIONALE

Republic Act (RA) No. 3720, as further amended by Executive Order (EO) No. 175 and RA No. 9711 otherwise known as the *"Food and Drug Administration (FDA) Act of 2009"* declared it as a policy of the State to adopt, support, establish, institutionalize, improve, and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health product regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to inspection, licensing, and monitoring of establishments, and the registration and monitoring of health products.

The aforesaid laws, including other FDA-implemented health laws, thus, have for their objectives: (a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction; (b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; (c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction; (d) Protect the public from food-borne and water-borne illnesses and unsanitary, unwholesome, misbranded, or adulterated foods; and (e) Enhance industry and consumer confidence in the food regulatory system.

In 2018, RA No. 11032, otherwise known as the *"Ease of Doing Business and Efficient Government Service Delivery Act"* was issued, promoting a re-engineered and simplified transactions in the government. Hence, the FDA, established a unified licensing guidelines to adopt a more harmonized licensing system across all health product establishments under its jurisdiction through the issuance of Department of Health (DOH) Administrative Order (AO) No. 2020-0017, otherwise known as the *"Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003"*.

However, amendment to existing FDA licensing regulations is necessary to update the list of technical and documentary requirements that shall be complied with by FDA regulated entities. These requirements are necessary for the evaluation of technical compliance and inspection of covered establishments to ensure that only safe health products are granted market access.

Further, to address emerging concerns and to be abreast with internationally acceptable standards and in keeping with its vision, the FDA's relentless effort to enhance its regulatory

capacity and strengthen its capability with regard to licensing, inspection, and monitoring of covered establishments is in order. Hence, in addition to the foregoing and under authority of Sections 3 (a) and (b), and Section 26 (a) of Republic Act No. 3720, as amended respectively by Sections 4 and 19 of Executive Order No. 175; and Section 7, Chapter 2, and Section 3, Chapter I, Title IX, Book IV of Executive Order No. 292, this Administrative Order is hereby issued.

II. OBJECTIVES

The objectives for issuing this Administrative Order are as follows:

1. To further reengineer the FDA's processes and automate its system for initial, renewal, and variation applications for License to Operate (LTO) through the FDA eServices Portal System, affirming the integration of information and communication technologies to maximize a focus on risks, promote coordination and information-sharing and ensure an optimal use of FDA resources;

2. To update the list of documentary and other technical requirements for LTO applications, as well as the procedures that shall be complied with by FDA-covered establishments promoting transparency and to be abreast with internationally acceptable standards; and

3. To institutionalize a longer validity period of licenses to operate, as well as the appeal mechanism in the regulatory authorization processes.

III. SCOPE

A. The establishments covered by this Order, whether public or private, shall include, but not be limited to:

1. Manufacturers, including Packers/Repackers/Refurbishers;
2. Traders;
3. Distributors as Importers, Exporters, and/or Wholesalers;
4. Retailers of Medical and Health-Related Devices;
5. Pharmaceutical outlets, such as drugstores, pharmacies (community, or institutional); or *boticas*, and retail outlets for non-prescription drugs (RONPDs); and
6. Clinical Research Organizations (CROs) and Sponsors;

B. The scope of 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 but not limited to drug products for human use, biological drug products such as blood products and vaccines, radiopharmaceuticals and precursors, Advance Therapy Medicinal Products,

homeopathic products, medical gases, herbal and traditional medicines, orphan drugs, and veterinary drugs;

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 including food/dietary supplements, raw materials, ingredients, and food additives.

This does not preclude the FDA from updating the scope of covered establishments which by the nature of their activities and health products that may have an effect on health, require regulation as determined by FDA, and in accordance with rules and regulations.

C. The following shall NOT be covered by this Order, subject to the immediately preceding paragraph:

1. Organizers of national and international trade fairs and exhibits;
2. Manufacturers, Traders, or Distributors of toys for adult collector's items;
3. Licensing and inspection of Cosmetics/HUHS Manufacturers/Refillers;
4. Retailers of processed food products, cosmetics, and household/urban hazardous substances, including household/urban pesticides and toys and childcare articles;
5. Activities under the purview of Local Government Units including slaughterhouses or abattoirs, poultry dressing plants, fish ports, wet markets, groceries, convenience stores, supermarkets without wholesale activity for foods, school canteens and restaurants without manufacturing/repacking activity of prepacked foods, catering establishments, chandlers, water refilling stations, street food stalls including ambulant vending, food kiosks of prepacked foods, rice repackers or traders;
6. Institutions and companies procuring pharmaceutical products from local suppliers intended solely for vaccination of their constituents/employees and/or the medical mission conducted on a specific schedule of activity. These institutions and companies shall apply for a Special Permit with the FDA prior to their activities. In addition, a report of adverse event following immunization (AEFI) shall be submitted to the FDA following the vaccination/medical mission activity, as may be required under related and existing rules and regulations; and
7. Hospitals and Stem Cell Facilities engaged in the use of Human Cell Tissues (HCTs)/minimal manipulation.

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

1. Salt Manufacturers, Distributors, and Traders shall follow RA No. 8172 or the "ASIN Law" and its revised Implementing Rules and Regulations (IRR);
2. Bottled Water Manufacturers shall follow DOH-AO No. 18-A s. 1993 or the "Standards of Quality and Requirements for the Processing, Packaging, and Labelling of Bottled Drinking Water";

3. Radiation facilities shall follow DOH-AO No. 2020-0035 or the "Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorization" and DOH-AO No. 2022-0022 or the "Basic Radiation Protection and Safety Standards on the Use of Ionizing Radiation Devices in Planned Exposure Situations";
4. Operators of pest control for non-agricultural purposes shall follow DOH-AO No. 2019-0010 or the "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of their Training Providers";
5. Applicators of household/urban pesticides and their training providers shall follow DOH-AO No. 2019-0010;
6. Tobacco Manufacturers and Distributors including Importers;
7. Donors, organizations, or persons involved in donations, medical missions, and other humanitarian activities;
8. Internet transactions (except Online Ordering) shall follow RA No. 11967 or the Internet Transactions Act of 2023; and
9. Facilities covered by the DOH One Stop Shop Licensing System shall follow AO No. 2018-0016 or the Revised Guidelines in the Implementation of the One-Stop Shop Licensing System.

IV. DEFINITION OF TERMS

All the terms or words and phrases used herein that are already defined under RA No. 3720 as further amended by EO No. 175 and RA No. 9711, other related FDA-implemented health laws and their respective IRRs, for the purpose of implementing this Order, shall have the same meaning as defined therein. *Annex A* provides for the definitions of the non-exclusive list of terms and phrases.

V. GENERAL GUIDELINES

A. All covered establishments, whether public or private entities, shall first secure an LTO with the FDA before they can apply for product market authorizations [i.e. Certificate of Product Registration (CPR) or Certificate of Product Notification (CPN)] and engage in any FDA regulated activities involving health products.

B. All covered establishments shall ensure that health products they manufacture, distribute, import, export, offer for sale, sell, transfer, non-consumer use, promote, advertise, sponsor, or those subject for clinical trial, satisfy the requirements of FDA-implemented laws, rules and regulations relevant to their activities in the supply chain and that control systems are in place to prevent, eliminate, or reduce risks to consumers.

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

D. All covered establishments, shall at all times demonstrate compliance with the standards appropriate to their authorized activity(ies), including, but not limited to, Good Manufacturing Practices (GMP), Good Laboratory Practices, Good Clinical Practices, Good Distribution and Storage Practices (GDSP). They shall also be knowledgeable of the specific requirements of FDA-implemented laws, rules and regulations relevant to their activities in the supply chain and the procedures adopted by the FDA.

E. In case the health product has been banned or withdrawn for health and/or safety reasons in the country of origin or manufacture, the importer and distributor of the health product shall immediately undertake the necessary measures to ban its import, offer for sale, promotion, advertisement, sponsorship, sale, distribution, transfer, non-consumer use, or donation, and initiate its immediate recall, withdrawal, or seizure from the Philippine market.

F. All covered establishments shall report to the FDA any incident that reasonably indicates that the health product they either manufacture, import, export, distribute, sell, offer for sale, transfer, non-consumer use, promote, advertise, sponsor, or those subject for clinical trial has caused adverse effects or contributed to the death, serious illness or injury to a consumer, a patient, or any person.

G. All covered establishments that manufactured, imported, exported, distributed, sold, offered for sale, transferred, non-consumer used, promoted, advertised, sponsored, or those engaged in clinical trial of a health product declared by the FDA to be injurious, unsafe, or dangerous shall immediately recall, withdraw, seize, and/or ban the manufacture, import, offer for sale, promotion, advertisement, sponsorship, sale, distribution, transfer, non-consumer use, and/or donation to the public, or from further clinical trial study.

H. Drugs, Medical Devices, and Cosmetic/HUHS Manufacturers, Traders, and Distributors shall declare on their applications the list of sources/authorized suppliers/clients and the respective types and/or name of finished products, semi-finished, raw materials, active pharmaceutical ingredients (in case of drugs), and excipients that are relevant to their activity/ies subject of application.

For FBOs, the existing rules under AO No. 2014-0029 or the Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and for Other Purposes and its amendment or revision shall apply.

I. Any changes on the previous list of sources/authorized suppliers/clients shall be considered as a minor variation and shall follow the process on variation application. Failure to declare the change and proceed with the process on variation shall subject the license, registration of the covered health product, or the application to Section 4, Article 1, Book II of the IRR of 9711, or to other regulatory and enforcement actions as determined by FDA.

J. The FDA shall have the authority to enter, at reasonable hours, any covered establishments, including facility(ies), factory, warehouses used in FDA-regulated activities, or vehicle, in which health products are manufactured, processed, packed,

or held, for introduction into domestic commerce, to conduct routine or spot check inspections of the premises and all pertinent equipment, finished or unfinished materials, containers, and labeling therein.

Whenever necessary, appropriate, and solely as an evidence on the inspection conducted, take copies of documents related to the covered activity(ies) subject of inspection, or capture photographs, obtain voice or video recordings of documents or the premises and/or equipment subject to the rules on confidentiality.

K. Related trainings or seminar shall, preferably, be FDA-initiated. Until a specific regulation for accreditation is established, the qualified person or, in case of FBOs, the owner shall submit proof of training or seminar (i.e. Certificate of Completion of training) from other reputable institutions offering technical courses relevant to their establishment and activity. Such training must have been conducted not more than two (2) years reckoned from the date of submission of application for LTO.

L. Corresponding fees and other charges for initial, renewal, or variations applications shall be governed by existing FDA-implemented fees and charges issuances.

M. In case the cause of delay in the processing of applications is due to force majeure or fortuitous events, which result in damage or destruction of documents, and/or system failure of the electronic processing, the prescribed processing timelines shall be suspended, and appropriate adjustments shall be made, provided the same shall be made known to the affected applicants or stakeholders.

On the part of the applicant, any delay of compliance on grounds of force majeure or fortuitous events may be allowed unless fully supported by evidence subject to further evaluation and disposition by the FDA.

N. The foregoing general guidelines are non-exclusive and shall not preclude the FDA from performing other regulatory and enforcement activities, and the covered establishments to allow inspection of their regulated activities and collaborate with the FDA authorities on action taken for consumer protection, as may be authorized by law, other rules, and regulations.

VI. SPECIFIC GUIDELINES

A. The following establishments shall comply with the stipulated conditions below:

1. **For Pharmaceutical establishments:**

    a. The requirement of a registered and licensed pharmacists supervision when operating or open for business as provided under Section 31 of R.A. No. 10918, otherwise known as the "Philippine Pharmacy Act" and its implementing Rules and regulations, are hereby adopted and implemented as follows:

i. **Category A** – Pharmaceutical outlets where the direct and immediate control and supervision of a duly registered and licensed pharmacist is required, per establishment, whether in-store or online, including:

(1) Pharmaceutical outlets selling or otherwise making available to the consuming public prescription/ethical medicines, combination products (medical device and drugs) classified as drugs according to the primary intended mode of action, pharmacist-only OTC medicine, whether owned by the government or by a private person or firm, whether sold at wholesale or retail;

(2) Establishments involved in the manufacture, importation, exportation, distribution, and sale of combination products (medical device and drugs) classified as drugs according to the primary intended mode of action;

(3) Departments/Divisions/Units of pharmaceutical laboratories, pharmaceutical manufacturing laboratories, or other establishments with processes involving the preparation, manufacture, assay, regulation, product research and development, quality control, repacking, importation, exportation, distribution, sale, or transfer of pharmaceutical products in quantities greatly in excess of single therapeutic doses; and

(4) Government units, including local government, city, first to third class municipal health units, non-government organizations and/or associations involved in the procurement, distribution, dispensing and storage of pharmaceutical products.

For purposes of this Category A, direct and immediate control and supervision of a pharmacist shall mean personal presence of the pharmacist every time the establishment is open for business.

ii. **Category B** – Pharmaceutical outlets where the supervision and oversight of a pharmacist is required under pertinent provisions of the law including:

(1) Pharmaceutical outlets selling household remedies and OTC drugs as differentiated from the pharmacist-only OTC medicines;

(2) Satellite institutional pharmacies providing medicines solely to employees of their respective companies or the employees' qualified dependents, or both; or members of a duly registered organization or institution;

(3) Fourth, fifth and sixth class municipal health units involved in the procurement, distribution, dispensing, and storage of pharmaceutical products;

(4) Institutions providing telepharmacy services; and

(5) Non-traditional outlets of pharmaceutical products: Provided, that no prescription medicines and pharmacist-only OTC medicines are sold.

For purposes of this Category B, supervision and oversight of a pharmacist shall mean the duty of looking after the operation of the establishment for proper direction or control in relation to the practice of pharmacist, but not necessarily in the strict sense of personal presence when the establishment is open for business.

The FDA, in coordination with the Board of Pharmacy, and the approval of the Professional Regulation Commission, may add to, delete, reclassify, or modify the above list of establishments, as the need arises, in order to keep pace with the developments in the pharmacy practice.

A pharmacist working in a Category A establishment may be allowed to simultaneously work or render pharmacy services in Category B establishments, the maximum number of hours of which shall be determined, in accordance with such guidelines as may be established therefore by the Board of Pharmacy, in coordination with the FDA, and other agencies, establishments, institutions, and regulatory bodies.

Procurement, storage, distribution, or dispensing of any pharmaceutical product in the national government and local government units shall be made only under the supervision of a duly registered and licensed pharmacist.

All units or sub-units of establishments, institutions, and regulatory bodies whether government or private with functions and activities that are exclusive for pharmacists, as defined in Section 4, paragraphs (a), (b), (c), (d) and (i) of RA No. 10918 shall be headed and managed by a qualified duly registered and licensed pharmacist; Provided, that an appointment in government service shall comply with the provisions of other pertinent laws.

b. All Pharmaceutical Manufacturers including Packers and Repackers may respectively engage in sub-contracting activities which is referred to as contract manufacturing/packing/repacking. Provided that the FDA must be notified and the engagement authorized by the FDA.

c. Only Pharmaceutical outlet licensed or authorized by the FDA shall compound, sell, offer for sale, or dispense any pharmaceutical product to the consuming public.

d. All institutional pharmacies procuring drugs to be dispensed whether at a cost or as part of employee's benefits and/or its dependent must secure an LTO as drug outlet.

e. All entities, whether government or non-government, that procure drugs on wholesale basis from appropriate FDA-duly licensed drug establishments for distribution to their constituents shall be required to obtain a license as a drug

distributor. Only licensed manufacturers, importers, distributors, and wholesalers of pharmaceutical products are authorized to sell their products to duly licensed drug outlet.

f. No CRO or Sponsor shall be involved in the conduct of clinical trials without a license from the FDA. CROs or Sponsors with issued LTO may import/export investigational drug products and ancillaries for the exclusive use in the conduct of clinical trials.

g. All FDA-licensed pharmaceutical retailers (drugstore, pharmacy, botica) or RONPD that also offer to sell medical device products shall secure a separate LTO from the FDA as Retailer of Medical Devices.

h. All FDA-required information, including the pharmacist's Certificate of Registration (COR), and communication campaign materials must be prominently displayed in the establishment's conspicuous area.

i. All pharmaceutical outlets shall, at all times comply with the following, such as but not limited to:

   i. Designate dispensing areas that are sufficiently secured to prevent unauthorized access during operating hours. This is also to ensure the safekeeping of specified health products to be supplied or dispensed by retail at or from the drugstores;

   ii. Applicable establishment layouts that allow for the orderly arrangement of specified health products to be supplied or dispensed by retail at or from the drugstores;

   iii. Appropriate storage facilities in accordance with the conditions approved by the FDA for the storage of specified pharmaceutical products; and

2. For Cosmetic/HUHS establishments:

All refilling activities involving cosmetics or HUHS shall only be applied as a Cosmetic/HUHS Manufacturer.

3. For Food Business Operators (FBOs):

a. All covered FBOs shall comply with the current guidelines on the principles and requirements of good manufacturing and hygienic practices, mandatory standards and national regulations for food including the provisions provided for by Presidential Decree No. 856 or the Code on Sanitation of the Philippines and RA No. 10611 or the Food Safety Act of 2013.

b. As far as appropriate, all FBOs shall comply with the relevant standards and requirements of Hazard Analysis Critical Control Point, Sanitary Standard Operating Procedures, and other good practice regulations and guidelines.

c. An LTO is a requirement before an FBO can join food trade and exhibitions, conduct market research, or laboratory test/analysis of processed food products.

4. For Medical Device establishments:

a. The following establishments are considered manufacturers of medical devices and are required to apply for an LTO:

i. All hospitals or establishments engaged in the 3D printing of medical devices;

ii. Optical establishments engaged in the assembly of optical lenses and frames; and

iii. Dental laboratories engage in the manufacture of custom-made dental devices.

b. All establishments handling medical devices which are considered "For Research Use Only" shall secure an LTO from the FDA as Medical Device Distributor-Importer".

c. For Optical Shop that retail ophthalmic lenses, prisms, contact lenses, and their accessories and solutions, low vision aids, and similar appliances and devices, wherein dispensing is governed by RA No. 8050, otherwise known as the "Revised Optometry Law of 1995", there shall be one (1) optometrist per branch/establishment.

i. The dispensing of these devices shall be performed by an optometrist;

ii. The optometrist may also be the qualified person of the establishment;

iii. The optometrist per branch/establishment shall always be available during operating hours. He/she may operate or work in more than 1 optical shop/clinic provided that his/her schedule shall not overlap with other branches.

iv. Establishment shall apply for a minor variation a change of its optometrist, provided that the optometrist is not the QP of the establishment.

B. The Qualified Person and Authorized Person of the establishments shall ensure compliance with the following:

1. All covered establishments shall have at least one (1) Qualified Person. The Qualified Person, 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, except for drug establishments following the requirement of registered and license pharmacist supervision provided under Section 31 of RA No. 10918 and its IRR.

2. Except for Pharmaceutical Manufacturer/Packer/Repacker and Retail Outlet under Category A, a single Qualified Person may be allowed by the FDA to handle a single establishment with multiple FDA-licensed activities under the same business name registration, ownership, office, and warehouse address; Provided, that the Qualified Person remains to sufficiently carry out his/her duties and responsibilities as provided in this Order.

3. Filing of applications and the authenticity of the documents to be filed shall be the responsibility and accountability of the Qualified Person and Authorized Person of the applicant establishment.

4. The Qualified Person shall ensure that all documentary and technical requirements and information provided in the application, together with all other submissions, including amendments, are true and correct based on existing records, legal documents, and other available information.

5. The Qualified Person shall ensure compliance of the establishment he/she represents with FDA procedural guidelines, the prescribed format and contents of administrative and technical documentary requirements, timely communications and coordination with the FDA pertaining to regulatory filings, post market surveillance, pre-licensing inspections and routine inspections, as well as continuous compliance of his/her establishment with regulatory standards, rules, and regulations.

6. The Qualified Person shall inform and apply for variation, either as major or minor, with the FDA of any changes in the submitted documentary and technical requirements to ensure the establishment's continuous compliance with the FDA is properly observed at all times.

7. All consultants, liaison officers, or freelancers doing business with the establishment on FDA licensing transactions/processes shall not be considered as duly Authorized Person or Qualified Person.

8. The Qualified Person shall adhere, at all times, to the qualifications and credential requirements stipulated in *Annex C* of this Order.

VII. APPLICATION REQUIREMENTS

All the requirements identified below are continuing during the validity of the LTO. Non-compliance with any shall be deemed an outright deficiency(ies) in the requirements and therefore a violation of this Order, which shall warrant a regulatory action against the license or authority granted to the establishment.

A. REQUIREMENTS FOR INITIAL APPLICATION

1. Accomplished eApplication Form with Declaration and Undertaking;
2. Proof of Business Name Registration and FDA-regulated activity;

*Note:For establishment as a Franchisee, a **Notarized Franchise Agreement** shall also be submitted. The business name of the establishment reflected in the LTO may be based on the trade name indicated in the Franchise Agreement. A copy of the applicant shall also be presented during the conduct of inspection.*

3. For MSMEs, Certification from the Department of Trade and Industry as proof of their level of categorization;
4. Risk Management Plan;
5. For Manufacturer including Packers/Repackers/Refurbishers, Site Master File (SMF);
6. For Manufacturers (including Packers/Repackers/Refurbishers), Traders, Distributors (Importers, Exporters, Wholesalers), list of sources and authorized suppliers/clients; and

   *Note: The **Contract of Agreement(s)** between the applicant and its sources shall be presented during the conduct of inspection. See Annex B.*

   The list shall identify the name of source, address, and product list(categories) whether local or imported.

7. Payment of appropriate fees

B. REQUIREMENTS FOR RENEWAL APPLICATION

1. **Automatic Renewal** (Subject to exceptions provided in Annex E of this Order)

   a. Accomplished eApplication Form;
   b. The application is filed before the expiration date of the license;
   c. The prescribed renewal fee is paid upon filing of the application; and
   d. A sworn statement (Declaration and Undertaking) indicating no change or variation whatsoever in the establishment is attached to the application

2. **Regular Renewal**

   a. Accomplished eApplication Form with Declaration and Undertaking;
   b. For Manufacturers including Packers/Repackers/Refurbishers: a copy of valid GMP Certificate;
   c. For MSMEs, Updated Certification from the Department of Trade and Industry as to level of classification; and
   d. Payment of appropriate fees

      Note: Subject to the rules on surcharge as prescribed in Book II, Article I, Section 3.A of IRR of RA No. 9711 and consistent with Section VIII.F of this Order.

C. REQUIREMENTS FOR VARIATION APPLICATION

1. Accomplished eApplication Form with Declaration and Undertaking;
2. Documentary requirements depending on the variation applied for; and
3. Payment of appropriate fees

The guidance for the above requirements is attached as *Annex B* (Requirements for Initial and Renewal License to Operate Application), and *Annex D* (List of Requirements for Specific Variation in the LTO), respectively.

VIII. APPLICATION PROCEDURE

A. FILING OF APPLICATION

1. All covered establishments applying for initial, renewal, or variation shall submit their applications including the documentary requirements through the FDA eServices Portal System.

2. Only one (1) e-mail address of the establishment shall be used for online applications, communications, and/or compliances, as the case may be. The official e-mail address used shall be unalterable and the FDA shall not be held liable in any way for loss or breach of access to the official e-mail address.

   Any communication or compliance made outside of the official e-mail address shall not be considered authorized and shall be disregarded.

3. The applicant is expected to agree with the "Declaration and Undertaking" by clicking on the "I agree to the Declaration and Undertaking" tab in order to continue with the application.

4. The FDA eServices Portal System shall be accessible in accordance with the prevailing schedule of the FDA online systems. All applications shall be processed on a first-in-first-out basis.

5. The filed application through the FDA eServices Portal System shall be issued with the corresponding Order of Payment for pre-assessment fee.

B. PRE-ASSESSMENT

1. Pre-assessment shall be conducted to determine the completeness of the requirements specific to each submitted application. Incomplete submission shall not be accepted, and the application shall not proceed to the next step of the process. No pre-assessment shall be conducted by the FDA without proof of payment of the pre-assessment fee.

2. The receiving officer or employee shall perform a preliminary assessment of the application submitted with its supporting documents. The applicant shall receive any of the following result of pre-assessment through its official registered e-mail address:

   a. Issued Order of Payment for application fee with Reference Number indicating the fees to be paid (Refer to Section VIII.C below for the payment of fees); or

b. The deficiency(ies) based on the accompanying requirements in relation to the requirements prescribed in Section VII of this Order specific to the type of application. The applicant shall be prompted to file a new application with complete documentary requirements.

3. In case of system failure due to force majeure or fortuitous event, other official modes of notification (i.e., registered mail or personal delivery) shall be resorted to.

4. A successfully pre-assessed application is not equivalent to an approved application. The evaluation of the correctness and sufficiency of the submitted documentary requirements and compliance of the operation or activity of the applicant establishments with reference to existing administrative and technical standards, rules, and regulations shall be conducted only during the evaluation and inspection steps.

C. PAYMENT

Payment made by the applicant-establishment shall be specific only to the type of licensing application applied for. Refund or transfer of payments shall not be allowed in cases where services have already been rendered by FDA, even if the application have been cancelled or discontinued.

1. **Pre-assessment Fee**

   a. After the successful filing of the application, an Order of Payment for the pre-assessment fee shall be issued.

   b. The Order of Payment has a validity of ten (10) working days from the date of its issuance to the applicant.

      Non-payment after the lapse of the validity period shall automatically cancel the application and invalidate the Order of Payment. The applicant shall be prompted to file a new application with complete documentary requirements and shall undergo pre-assessment process.

   c. Payment of the prescribed pre-assessment fee as indicated in the Order of Payment, exclusive of bank charges, if any, shall be done through the payment channels which can be accessed through the FDA eServices Portal System. Refer to *Annex F* of this Order for the FDA payment procedure for licensing applications.

2. **Application Fee**

   a. For successfully pre-assessed applications, the pre-assessment fee paid shall be deducted from the total application fee due.

   b. Payment of the prescribed application fee [including Legal Research Fund (based on the application and pre-assessment fees) and applicable surcharges] as indicated in the Order of Payment, exclusive of bank charges, for

successfully pre-assessed application shall be done through the payment channels which can be accessed through the FDA eServices Portal System. Refer to *Annex F* of this Order for the FDA payment channels for licensing applications.

The Order of Payment has a validity of ten (10) working days from the date of its issuance to the applicant.

i. Non-payment after the lapse of the validity period shall automatically disapprove the application and forfeit the pre-assessment fee paid. The applicant shall be issued a notice of disapproval due to non-payment within the prescribed validity period of the Order of Payment. The disapproval is final. The applicant shall file a new application with complete documentary requirements and shall undergo pre-assessment process.

ii. In case of renewal applications, where the non-payment after the lapse of the validity period coincides with the expiration of the LTO, the rules on surcharge shall also apply. The applicant shall also be prompted (system-generated) to file a new application with complete documentary requirements and shall undergo pre-assessment process.

Refer to *Annex G* on the rules on renewal application fees and surcharges.

3. **Acknowledgement of Payment for Application Fee**

For applications with complete documentary requirements and posted payment, the FDA shall issue an acknowledgement receipt and the application shall be considered filed once it is received by the applicant. The acknowledgement receipt is deemed received by the applicant after three (3) calendar days from its issue unless earlier confirmed by the applicant.

The FDA may issue further guidelines for matters involving payment.

D. REGULATORY INSPECTION

The FDA shall have the authority to enter any covered establishments including facility(ies), factory, or warehouses, including vehicles used in FDA-regulated activities involving health products during operating hours to conduct regulatory inspections. Whenever necessary, appropriate, and solely as an evidence on the inspection conducted, take copies of documents related to the covered activity(ies) subject of inspection, or capture photographs, obtain voice or video recordings of documents or the premises and/or equipment subject to the rules on confidentiality.

All covered establishments shall allow inspection of their businesses, physical sites, premises, and all pertinent equipment, finished or unfinished materials, containers, and labeling therein. They shall collaborate with the FDA on action taken to avoid risks posed by the health product(s) that they have manufactured, distributed, or sold.

Regulatory Inspections may consist of the following:

1. **Pre-licensing Inspection**

   a. Subject to paragraph C of the Transitory Provision, the conduct of pre-licensing inspection to all FDA-covered establishments under Section III.A of this Order applying for initial or applicable major variations shall be required. Verification for compliance with technical requirements and applicable standards of the establishments shall be conducted in accordance with the applicable procedures and timelines of the FDA.

   b. For minor variation applications, no pre-licensing inspection is required. Establishments with approved minor variation applications shall be subject to inspection on the scheduled annual inspection or sooner as directed by the FDA.

   c. Scheduling and pre-inspection shall only be conducted upon payment of the required fees and posting of payment.

   d. The applicant shall be notified of the confirmed date and manner of inspection through an official "Notice of Inspection" letter from the FDA. The date of the inspection determined by the FDA shall be final. The applicant shall have a period of three (3) calendar days within which to acknowledge receipt of the Notice of Inspection otherwise it is deemed received.

   e. The conduct of inspection including the issuance of regulatory decisions shall be completed within the timelines prescribed in the latest citizen's charter of the FDA.

   f. Any findings during inspection requiring the submission of responsive Corrective and Preventive Actions (CAPA) from the applicant shall suspend the running of the inspection timeline. The timeline covering the CAPA implementation and subsequent verification by FDA, as necessary, shall be covered by appropriate FDA issuance.

   g. Except in cases of force majeure or fortuitous event, any request by the applicant for cancellation or rescheduling of the inspection shall forfeit any paid application fee and a new application shall be filed following the requirements and processes specified above, and payment of a new application fee. Cancellation or rescheduling of the inspection by reason of force majeure or fortuitous event must be fully supported by evidence and shall be subject to further evaluation and disposition by the FDA.

   h. All covered establishments shall follow and show in a satisfactory manner its compliance with the applicable good practices and other standards (GxPs), including related laws, rules, and regulations implemented by the FDA.

   i. Risk categorization of manufacturers as determined by the FDA through appropriate issuances shall be declared by the applicant-establishment subject to verification by the FDA.

j. All covered establishments shall develop and make available all required documents for presentation during the conduct of inspection or when otherwise required by FDA.

k. Certificate of Compliance (COC) shall be issued, which shall be the basis for the issuance of LTO or approval of the major variation application upon determination of satisfactory compliance to documentary and technical requirements.

l. Recommendation Letter shall be issued as basis for automatic renewal application or approval of minor variations, also, upon determination of compliance to the FDA requirements and none of the identified exception in case of automatic renewals as provided in *Annex E*.

2. Routine Inspection

a. Routine inspections shall be undertaken for all types of establishments within the validity of the LTO.

b. The frequency of subsequent inspections shall be based on the FDA-established risk assessment and risk rating derived from the immediately preceding inspection conducted, unless earlier inspection is required due to other conditions as maybe determined by the FDA.

c. Continuing compliance of covered establishment shall be determined following the requirements under this Order, applicable good practices and other standards (GxPs), including related laws, rules, and regulations.

d. All covered establishments shall make available all required documents for presentation during the conduct of inspection or when otherwise required by FDA.

e. Findings during inspection requiring the submission of responsive CAPA, the rule in Section VIII.D.1.f of this Order shall apply.

f. Other regulatory remedies may be pursued by the FDA as deemed appropriate and in accordance with applicable rules and regulations.

3. Other types of Inspection

Notwithstanding any prior inspection conducted, the FDA shall not be precluded from pursuing other types of inspection (i.e., investigation, monitoring, special assignments, audits) and regulatory or enforcement actions as deemed necessary to prevent health risks to consumers or when public health and safety requires otherwise.

E. EVALUATION PROCESS

1. Upon receipt of the COC along with the application, the assigned FDA evaluator shall conduct a detailed evaluation of the correctness and substance of the specified documentary requirements supplied by the applicants, and an assessment of the inspection reports together with other available and related regulatory information.

2. Evaluation shall be done within the timelines prescribed in the latest citizen's charter of the FDA.

3. The total processing time as prescribed in the citizen's charter may be extended only once for the number of days of extension prescribed in the Citizen's Charter.

4. Prior to the lapse of the initial processing period, the concerned office of the FDA shall notify the applicant in writing and be sent to the official e-mail address of the applicant. The applicant shall have a period of 3 calendar days within which to acknowledge receipt of the notice otherwise it is deemed received and have concurred to the extension.

5. In case where the cause of delay is due to force majeure or fortuitous events which result to damage or destruction of documents, and/or system failure of the computerized processing, the prescribed processing times shall be suspended and appropriate adjustments shall be made, provided the same shall be made known to the affected applicants or stakeholders.

F. RENEWAL APPLICATIONS

1. Automatic Renewal

a. An application for automatic renewal shall be made within three (3) months prior to the expiration of the validity date of the LTO.

b. Exceptions to the application for Automatic Renewal are enumerated under *Annex E* of this Order.

2. Regular Renewal

a. An application for renewal shall be made within ninety (90) calendar days prior to the expiration of the validity date of the LTO.

b. Where the establishment has made timely and sufficient application for renewal of its license with reference to any activity of a continuing nature, the existing license shall not expire until regulatory decision on the application shall have been determined by the FDA.

c. Applications filed after the validity date of the LTO shall be subject to a surcharge as prescribed in the IRR of RA No. 9711 and FDA Circular No. 2011-004 or the "Computation of Surcharge or Penalty Imposable in Case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraph (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes".

An application for renewal of an LTO received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal licensing fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days.

Any application for renewal of license filed thereafter shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure.

For applications for renewal filed within one hundred twenty (120) days from its original expiry, the LTO shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

G. VARIATION APPLICATIONS

1. All variations or change shall be applied before the FDA. Variations are categorized either as major or minor. The types of variations falling under each category are listed in *Annex D* of this Order.

2. All covered establishments shall inform the FDA of any changes or variations made to its license and authorized activity, and a corresponding variation application shall likewise be filed for the issuance of an LTO reflecting the changes or variations made.

3. 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, or if the validity of the license is beyond its expiration date as reflected in the LTO.

4. The transfer of location of a manufacturing/packing/repacking/refurbishing plant is considered as major variation for Manufacturer/Packer/Repacker/Refurbisher with an application fee equivalent to an initial application.

5. The procedures on filing of variation application shall follow the procedures on pre-assessment, inspection, and evaluation in so far as applicable.

H. CHECKING OF APPLICATION STATUS

In accordance with the Zero-Contact policy provided under RA No. 11032, the status of the application shall be checked and verified through the FDA eServices Portal System.

I. RELEASING AND PRINTING OF LTO

1. The existing process of FDA in sending the approved LTO to the official registered e-mail address shall be in effect until the FDA shall institutionalizes the use and procedures of implementing the FDA security seal.

2. Until then, the printing of the emailed and approved LTO shall be the sole responsibility of the owner of the establishment. The existing FDA policy not to re-issue or provide certified true copies of the authorization/s shall be in effect until otherwise superseded by another FDA issuance.

IX. DECISION ON THE APPLICATION

A decision on the application may consist of the following:

A. APPROVAL

Only upon a determination by the FDA of satisfactory compliance to the requirements after evaluation of the application and, in case of initial, major variation, or regular renewal application, findings of full conformity of the establishment with the applicable technical standards after inspection shall the application be granted, as the case may be. An LTO shall be issued or renewed with a corresponding scope of activity and validity as provided under Section VIII of this Order.

B. DISAPPROVAL

1. **Grounds for Disapproval of Application**

   a. Any of the following or similar instances shall be a ground for the disapproval of an application for LTO or variation thereof:

      i. The application requirements submitted and/or the inspection show that the establishment does not meet the requirements or appropriate standards;

         For purposes of this, non-submission of the required CAPA if any or non-implementation of the FDA-accepted CAPA within the approved timeline is deemed not meeting the requirements for appropriate standard.

      ii. The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the applicable FDA-implemented laws, Rules, and Regulations or appropriate standards;

      iii. The owner has violated any of the terms and conditions of its license in case of renewal applications;

      iv. Other analogous grounds or causes, such as but not limited to:

         (1) Failure to pay either the pre-assessment or application fee within the prescribed period;

         (2) The applicant refuses entry of FDA inspection officers or access to pertinent records upon request during inspection;

(3) The applicant or its officers connive with the inspection or evaluation officer, or other FDA officer related to findings during the conduct of evaluation or inspection, which may result in health product safety risks to the consumers.

(4) Findings of other violations of any other laws.

b. Every disapproval of an application rendered by the FDA shall be fully explained in writing, stating the name of the FDA Official making the denial and the ground(s) upon which such denial is based.

c. A disapprove application may be subject to a request for reconsideration.

2. **Releasing of Disapproved Application**

a. The applicant shall be notified of the disapproval, explained in writing, stating the name of the FDA official making the denial and the ground(s) upon which such disapproval is based, through the official e-mail address of the establishment.

b. The applicant establishment shall have a period of three (3) calendar days within which to acknowledge receipt of the Notice of Disapproval otherwise it is deemed received.

3. **Reconsideration on the Disapproved Application**

a. The applicant may opt to request for administrative reconsideration of the disapproval by filing with the Office of the Director General of the FDA, copy furnished the concerned office, a formal request for reconsideration within fifteen (15) calendar days after receipt of a copy of the decision disapproving the application and paying the required reconsideration fees as provided in the current FDA's schedule of fees and charges. No extension for filing of the request for reconsideration shall be entertained.

b. No request for reconsideration shall be entertained unless the reconsideration fee is paid. The procedure on payment of application fee shall be followed as far as applicable.

c. The applicant shall point specifically the findings or conclusions stipulated in the Notice of Disapproval which are not supported by facts, rules, or technical standards.

d. The FDA shall resolve the request for reconsideration within twenty (20) working days from receipt of the request for reconsideration.

The FDA shall publish and make available for public inspection, all final decisions of approved or disapproved applications for initial, renewal, or variations, including those with CAPA, subject to the rules on Freedom of Information and Data Privacy.

For the above purpose, the FDA shall endeavor to prepare a register or compilation of those decisions or final orders or reports.

X. VALIDITY OF THE LTO

A. The validity of the issued LTO shall be as follows:

VALIDITY OF LTO	Micro and Small Enterprises	Medium and Large Enterprises
INITIAL LTO	**3 YEARS**	**6 YEARS**
RENEWAL LTO	**6 YEARS**	**12 YEARS**

B. The validity of approved major and minor variations shall follow the remainder of the validity of the existing LTO reckoned from the date of the approval.

XI. SUSPENSION OR CANCELLATION/REVOCATION OF THE ISSUED LTO

A. Grounds for Suspension or Cancellation/Revocation

1. Except in cases of willful violation of FDA-implemented laws, rules, and regulations, or when public health or safety require otherwise, or when the establishment with previously issued LTO failed to file an application for renewal after one-hundred and twenty (120) days from the date of expiration, no LTO may be suspended, cancelled, or revoked without notice and hearing.

   In any of the instances in the preceding paragraph, the LTO may be automatically suspended, cancelled or revoked and the establishment shall, within forty-eight (48) hours from receipt of the order suspending, cancelling, or revoking the LTO without notice and hearing, show cause as to why the said order should not remain in force. Thereafter, if the establishment contests such order, the case shall ensue following the Uniform Rules of Procedures under Book III of the IRR of RA No. 9711 for purposes of whether or not the explanation of the establishment will be sustained, or the initial regulatory action will be maintained, and further appropriate penalty shall be imposed.

2. In other instances, any issued LTO shall be suspended, cancelled, or revoked, after notice and hearing, based on any of the following grounds:

   a. The application requirements submitted show that the establishment does not meet the required technical requirements or appropriate standards;

   b. The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the FDA-implemented laws, their IRR, or appropriate standards;

   c. The owner has violated any of the terms and conditions of its license;

   d. Other analogous grounds or causes, such as but not limited to:

i. Non-existence of the physical site at the declared address; and

ii. Violations of any of those prohibited acts identified under Republic Act No. 3720, as amended by Executive Order No. 175 and Republic Act No. 9711 or other FDA-implemented laws, rules, and regulations.

3. The suspension of the validity of the License To operate shall not exceed one (1) year.

4. The Uniform Rules of Procedures under Book III of the IRR of RA No. 9711 shall apply unless a particular rule of procedure is provided by the other FDA-implemented laws.

5. Nothing in this section shall restrict the FDA in enforcing the other imposable penalties provided under the applicable FDA-implemented laws, rules, and regulations.

B. Voluntary Cancellation of Existing LTO

Voluntary cancellation of the license holder of its existing LTO may be allowed through the filing a formal notification before the FDA, following the procedure of applying for major variation, and payment of appropriate fees. Provided the voluntary cancellation is not intended to defraud the government, the license holder's creditors, and/or its workers. Provided further that any act of voluntary cancellation shall not remove the FDA of jurisdiction or preclude it in pursuing acts of ensuring the safety of the public or regulatory, enforcement, or other actions as a result of violation or non-conformance of the license holder with FDA-implemented laws, standards, rules and regulations.

No clearance or affirmation of the voluntary cancellation of the existing LTO shall be made unless any FDA-related obligation of the license holder is settled or unless restrained by the Secretary of Health or the Court.

Verification through inspection or other mode prior to clearance or affirmation may be pursued as determined by the FDA.

C. Effect of LTO Suspension, Cancellation, or Revocation

1. Any suspended, cancelled, or revoked LTO shall have the effect of non-possession of an LTO of an establishment. Thus, the validity of any issued and existing Certificate of Product Registration or Notification shall be automatically affected and any further manufacture, importation, distribution, wholesale of covered health products, and retail (in case of drugs and devices) are deemed prohibited.

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

XII. TRANSITORY PROVISION

A. All existing and pending applications for LTO of establishments enumerated in Section III received prior to the effectivity date of this Order shall be processed according to DOH AO No. 2020-0017 until all are exhausted.

B. All major and minor variation applications received upon the effectivity of this Order for LTOs previously issued based on DOH AO No. 2020-0017 shall be subject to the updated guidelines as stipulated in this Order.

C. Pre-licensing inspections for all health product manufacturers is maintained and other drug establishments is required from effectivity of this Order. Within five (5) years from the coming into force of this Administrative Order, pre-licensing inspection shall be required to other health product establishments. The FDA shall issue the corresponding notice for the implementation of the pre-licensing inspection if shorter than the 5-year period.

D. The variation for the list of sources/authorized suppliers/clients shall be effective immediately for drug establishments upon effectivity of this Order. For other health products, a 1-year transitory period from the effectivity of this Order shall be applied.

E. A pilot run shall be implemented from the effectivity of this Order involving stakeholders and for a period as determined by the FDA but shall no longer be six (6) months.

XIII. REPEALING CLAUSE

Except for purposes of application of paragraphs A and E of Section XII above, DOH 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" is hereby repealed.

Other issuances or parts thereof, pertaining to specific guidelines for certain establishments which are found to be inconsistent with the provisions of this AO are hereby repealed accordingly.

XIV. SEPARABILITY CLAUSE

If any portion or provision of this Order is declared invalid, 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.

XV. EFFECTIVITY

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

TEODORO J. HERBOSA, MD
Secretary of Health