Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary

BAGONG PILIPINAS

ADMINISTRATIVE ORDER
No. 2024-0015

NOV 22 2024

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 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 these laws, 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 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 re-engineered and simplified transactions in the government. Hence, the FDA revised the unified licensing guidelines to adopt a more harmonized licensing system across all health product establishments 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 Food and Drug Administration Repealing Administrative Order No. 2016-0003"*.

Therefore, there is a need to improve the FDA's structures, processes, mechanisms, and initiatives in so far as the existing FDA licensing regulations such as updating the list of technical and documentary requirements that shall be complied with by entities covered under this Order. 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 regarding 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 of Book IV, and Section 3, Chapter 1, Title IX of the same Book IV of Executive Order No. 292, this Administrative Order is hereby issued.

II. OBJECTIVES

The objectives of this Administrative Order are as follows:

A. To prescribe the updated rules, requirements, and procedures for initial, renewal, and variation License to Operate (LTO) application through the FDA eServices Portal System;

B. To be abreast with internationally acceptable standards and new local legislations in further improving the structures, processes, and mechanisms for LTO application and the integration of information and communication technology to maximize a focus on risks, promoting faster coordination and information-sharing ensuring optimal use of FDA resources; and

C. To institutionalize a longer validity period of licenses to operate, as well as the administrative reconsideration mechanism in the regulatory licensing processes.

III. SCOPE

A. This Administrative Order shall be implemented by FDA over the following establishments, whether public or private:

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);
6. Veterinary Pharmaceutical Retailers and other veterinary product establishments; and
7. Contract Research Organizations (CROs) and Sponsors;

B. The scope of health products shall include the following:

1. Cosmetic products, household/urban hazardous substances (HUHS), including household/urban pesticides, and toys and childcare articles;

2. Pharmaceutical products for human and veterinary use, including but not limited to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical specialties, veterinary products, biologics and medicinal products, advance therapy medicinal products, homeopathic products, medical gases, herbal and traditional

medicines, and orphan drugs, as well as active pharmaceutical ingredients or drug substances;

3. 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. 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 and health products which affect health that require regulations as determined by FDA, and in accordance with laws, 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 in so far as the organization of the trade fair per se is concerned;
2. Manufacturers, Traders, or Distributors of toys for adult collector's items;
3. Licensing and related inspection of Cosmetics/HUHS Refillers;
4. Retailers (offline or online) of processed food products, cosmetics, and household/urban hazardous substances, including household/urban pesticides and toys and childcare articles. However, the products sold at retail shall be subject to post marketing surveillance;
5. Activities under the purview of Local Government Units including slaughterhouses or abattoirs, poultry dressing plants, fish ports, wet markets, 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;

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) including its amendments;
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" and its amendments;
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" and their amendments;

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" and its amendments;
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 which is covered by this Order) shall follow RA No. 11967 or the Internet Transactions Act of 2023 and its amendments;
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 and its amendments; and
10. Hospitals and Stem Cell Facilities engaged in the use of Human Cell Tissues (HCTs) following AO No. 2013-0012 or the "Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell-Based or Cellular Therapies in the Philippines" and FDA Circular 2013-017 or the "Registration of Human Stem Cell-Based Products" and their amendments.

IV. DEFINITION OF TERMS

All the terms or words and phrases used herein that are already defined under RA No. 3720 as 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 the definitions of the non-exclusive list of terms and phrases used in this Order.

V. GENERAL GUIDELINES

A. All covered establishments, whether public or private entities, shall first secure or shall have a valid LTO with the FDA before they can apply for and be granted other 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, at all times, guarantee their operation's compliance to regulations relevant to their activities in the supply chain; 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 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 always 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. All pharmaceutical products, medical devices, biological, and medical supplies establishments covered by Administrative Order No. 2021-0036 or its revision or supplement shall strictly comply with the requirements and process of submitting written disclosure report to FDA pertaining to all financial relationships between manufacturers, traders, repackers, distributor-importers, and distributor-wholesalers of FDA-registered drugs, biologicals, medical devices, and other medical supplies and health care providers.

F. 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 banned or withdrawn health product shall immediately report the case to FDA and 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.

G. 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.

H. 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.

I. Drugs, Medical Devices, and Cosmetic/HUHS Manufacturers, Traders, and Distributors shall declare in their applications the list of sources/authorized suppliers 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 Food Business Operators (FBOs), applications for the list of sources/authorized suppliers shall follow 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.

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

K. The FDA shall have the authority to enter, at reasonable hours, any covered establishments, including facility(ies), factory(ies), 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 evidence on the inspection conducted, the FDA may 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 or the rules on data privacy based on RA No. 10173 or the Data Privacy Act of 2012.

L. Related trainings or seminars 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.

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

N. 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.

O. 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.

P. The Annexes of this Order may be subject to amendment, modification, revision, or supplement by the FDA, through the proper FDA issuance, subject to its internal rules on policy development and coordination with the DOH.

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 pharmacist's 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 under Rule IV thereof, 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 more than the 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 non-prescription/OTC medicine 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 Professional Regulatory 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, 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 licensed manufacturers, importers distributors, and wholesalers of pharmaceutical products are authorized to sell their products to duly licensed pharmaceutical outlets.

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

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

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

g. No pharmaceutical retailer/outlet shall conduct online ordering and selling activities without a valid LTO. Provided further, that any internet transactions of pharmaceutical retailer/outlet shall comply with existing internet, eCommerce, and other relevant laws, rules, and regulations.

h. All FDA-licensed pharmaceutical retailers (drugstore, pharmacy, botica) or retail outlet for non-prescription drugs that also offer to sell medical device products shall secure a separate LTO from the FDA as Retailer of Medical Devices.

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

j. 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;

k. 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 pharmaceutical products and ancillaries for the exclusive use in the conduct of clinical trials.

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 and secure 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".

For Optical Shops, ophthalmic lenses, prisms, contact lenses and their accessories and solutions, frames and their accessories, and supplies for the purpose of correcting and treating defects, deficiencies and abnormalities of vision shall only be prescribed and dispensed by a licensed optometrist as governed by RA No. 8050, otherwise known as the "Revised Optometry Law of 1995". The optometrist may also be the qualified person 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 pharmaceutical 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, Authorized Person, and 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, or notification, as the case may be with the FDA of any changes in the status of the establishment, its previously authorized activities, among others, and submit the corresponding documentary and technical requirements to ensure the establishment's continuous compliance with the FDA requirements and standards 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. All Qualified Persons shall ensure compliance with applicable training relating to the health product and health product establishments they are associated with.

9. 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 in Annex B 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 including any other authorization issued where the LTO is one of the requirements (i.e. GMP, CPR/CPN).

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) official 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 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 and Annex B 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 has 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 a 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 a pre-assessment process.

ii. In the 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 reasonable hours to conduct regulatory inspections.

Whenever necessary, appropriate, and solely as evidence on the inspection conducted, the authorized FDA inspectors may 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 or the rules on data privacy based on RA No. 10173.

All covered establishments shall allow inspection of their businesses, physical sites, premises, and all pertinent copies of documents, 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, offered for sale, or sold.

Regulatory inspections may either be on-site, remote, or hybrid, the specific guidelines of which shall be adhered to as provided by the FDA.

Establishments shall not be precluded from utilizing virtual offices; 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.

Provided further, that any internet transactions of covered establishments shall comply with existing internet, eCommerce, and other relevant laws, rules, and regulations. 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 FDA.

Regulatory Inspections may consist of the following:

1. **Pre-licensing Inspection**

   a. Subject to paragraph C of Section XII 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 of the establishments with technical requirements and applicable standards shall be conducted according to 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 five (5) calendar days prior to the confirmed date 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 three calendar days 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 shall 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 by the FDA, 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 by the FDA 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 thereafter 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. Before the initial processing period lapses, 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 filed through the eServices Portal System made within 90 (ninety) calendar days 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 filed through the eServices Portal System 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" or their supplement or amendment as the case may be.

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.

Refer to Annex G on the rules on surcharges.

G. VARIATION APPLICATION

1. All variations or changes 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 except on the change or addition of sources.

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 FDA shall send the approved LTO to the official registered e-mail address of the applicant.

2. Printing the emailed and approved LTO shall be the sole responsibility of the establishment's owner. 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 and Section X, respectively, 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 as provided in item number 3 of this section.

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 to 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 as reflected in Executive Order No. 2 Series 2016 and Data Privacy based on RA No. 10173.

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

C. The validity period of CPR/CPN of establishments with valid LTO shall be determined by the FDA through appropriate regulation, which in no case shall exceed the validity of the existing LTO.

D. The fees for LTO and CPR/CPN are based on a yearly rate and shall be multiplied by the allowable number of years of validity consistent with the preceding paragraph.

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 six (6) working days 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 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; or

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 LTO 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 such as but not limited to fine after notice and hearing, provided under the applicable FDA-implemented laws, rules, and regulations, for violation of any provisions of this Order.

B. Voluntary Cancellation of Existing LTO

1. Voluntary cancellation of the license holder of its existing LTO may be allowed through the filing of 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 because of violation or non-conformance of the license holder with FDA-implemented laws, standards, rules and regulations.

2. 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.

3. 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 or other authorizations where a valid LTO is a requirement shall be automatically affected and any further

manufacture, importation, distribution, wholesale of covered health products, and retail (in case of pharmaceutical products 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.A 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 inspection for all health product manufacturers is maintained and other pharmaceutical establishments are 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 it is shorter than the 5-year period.

D. The variation for the list of sources/authorized suppliers/clients shall be effective immediately for pharmaceutical 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 two-year transitory period from the effectivity of this Order shall be given to other veterinary establishments such as pet shops, pet grooming/salon shops, and pet hotels, supermarkets and stores, veterinary agricultural, agricultural supply store, livestock, and poultry supply stores to comply with this Order.

F. 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 F 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 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

CERTIFIED TRUE COPY
NOV 26 2024
CORAZON S. DELA CRUZ
AS - RECORDS SECTION
Department of Health

ANNEX A

DEFINITION OF TERMS

The following terms or words and phrases shall mean or be understood as follows:

A. **Advance Therapy Medicinal Product (ATMP) for human use** – refers to any cell or gene therapy product or tissue engineered product that has been substantially manipulated and/or performs a different function in the recipient than in the donor. Although typically produced from substantially manipulated or genetically modified somatic cells or tissues, ATMPs may also include nucleic acids, and viral and non-viral vectors, as well as recombinant bacterial cells and recombinant oncolytic viruses.

B. **Authorized Person** - refers to the owner, President, Chief Executive Officers (CEO), manager, or its equivalent officer representing the establishment in an authorized or official capacity as signatories to required documents for purposes of filing of covered applications before the FDA.

C. **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).

D. **Contracting** – refers to the formal and documented evidence of activities, including such other activities included in this AO, undertaken by the contract acceptor (referred to as Contract Manufacturer including Packer and Repacker) to its contract giver (referred to as its Client) with regard to the manufacturing/packing/repacking of the client.

E. **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.

F. **Declaration and Undertaking** – refers to a binding agreement of the applicant-establishment with the FDA in providing accurate information, affirming primary responsibility over the products and facilities, and complying with all the rules and regulations set forth during and after the application process, among others. Declaration of false, other forms of misrepresentation, or withholding of data or information are grounds for disapproval of the application, or suspension or revocation of the issued authorization and may subject the person involved to criminal prosecution.

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

H. **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.

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

J. **Good Practice (GxP)** – refers to officially acceptable practices and standards in the conduct of health product activities such as but not limited to good manufacturing Practices (GMP), good laboratory practices (GLP), good clinical practices (GCP), guidelines on food hygiene and good distribution and storage practices (GDSP).

K. **Health-related device** – refers to any device not used in health care but has been determined by the FDA to adversely affect the health of the people.

L. **Initial Application** - refers to the type of LTO application submitted to the FDA prior to engaging in the business or operation involving the manufacture, importation, exportation, retail, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

M. **Institutional Pharmacy** – refers to pharmaceutical establishment which is a non–government entity/organization procuring pharmaceutical products to be dispensed whether at a cost or as part of employee's benefits and/or its dependents.

N. **License to Operate** – refers to an authorization issued by the FDA granting an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

O. **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.

P. **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. A trader shall be categorized as a manufacturer.

Q. **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, efficacy of the products.

R. **Micro Small Medium Enterprises (MSMEs)** - refers to any business activity or enterprise engaged in industry, agribusiness and/or services, whether single proprietorship, cooperative, partnership or corporation whose total assets, inclusive of those arising from loans but exclusive of the land on which the particular business entity's office, plant and equipment are situated, must have value falling under the following categories: a.) Micro, not more than P3,000,000, b.) Small, P3,000,001 but not more than P15,000,000, and c.) Medium, P15,000,001 but not more than P100,000,000. More than P100,000,000 is considered a large enterprise (RA No. 9501 or the Magna Carta for Micro, Small, and Medium Enterprises).

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

T. **Pre-licensing Inspection** – refers to an inspection performed prior to the approval of a license (initial application) or significant change (major variation) to facility(ies), warehouses, and/or offices of an establishment to ensure compliance to the provisions of this Order and to the other related FDA-implemented and existing regulations and standards.

U. **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, discuss or clarify matters with the FDA when submitting technical requirements, or engage FDA officials when conducting inspections or Post-Marketing Surveillance (PMS) activities. The qualified person may also be the duly Authorized Person of the establishment.

V. **Refurbisher** – refers to an establishment engaged in the rebuilt of certain medical device (in whole or any part thereof), whether or not using parts from one or more used certain medical devices of the 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.

W. **Renewal Application** - refers to the type of LTO application submitted to the FDA before the expiration of the validity of the current LTO for 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.

X. **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.

Y. **Request for Reconsideration** – refers to the process where an applicant formally requests and seeks a review or re-evaluation of a decision disapproving an application for initial licensing, renewal, or variation.

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

AA. **Risk Categorization on Establishment** is a classification system used to assess and categorize health product manufacturers based on the complexity of the site, the processes involved in production, and the types of health products manufactured. The classification can be low, medium, or high risk or their equivalence.

In case of more than one product line in a manufacturer with a different identified risk category, the highest risk shall prevail.

BB. **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 the effectiveness of those interventions. The risk management plan is a requirement for the issuance of the appropriate authorization.

CC. **Routine Inspection** - refers to the general process of physical or remote inspection of the factories, facility(ies), warehouses, and/or offices of an establishment in which health products are manufactured, processed, packed, or held, for introduction into domestic commerce or are held after such introduction, which is conducted by the FDA at any time during the validity of the issued LTO. A routine inspection is also referred to as a post-licensing inspection.

DD. **Site Master File** - refers to specific information about the quality assurance, 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 to describe those operations, e.g., analysis, packaging, for documentation.

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

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

GG. **Veterinary Pharmaceutical Retailer** – refers to any establishment which sells or offers to sell any veterinary drug product directly to the general public which includes, but not limited to:

1. Veterinary Clinics, pharmacies, veterinary hospitals where registered veterinary drug products, chemical products, active pharmaceutical proprietary medicines, or pharmaceutical specification are compounded and/or dispensed.

2. Other Veterinary Establishments such as pet shops, pet grooming/salon shops, pet hotels, supermarkets and stores, veterinary agricultural, agricultural supply store, livestock, and poultry supply stores where registered veterinary drug products are sold and dispensed.

HH. **Veterinary Establishment** – refers to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of veterinary drug products.

ANNEX B

A. REQUIREMENTS FOR INITIAL LICENSE TO OPERATE APPLICATION

1. **Accomplished eApplication Form with Declaration and Undertaking through the FDA eServices Portal System**

   Among other information, the applicant shall provide the following information:

   a. Global Positioning System (GPS) coordinates

   b. Name of the Qualified Person, depending on the type of health product establishment as specified in Annex C

   c. For Pharmacists handling Category A and B, list of all outlets including Name of Establishment, Address, plotted Geolocation, Day, and Time of shift and LTO number.

2. **Proof of Business Name Registration and FDA-Regulated Activity**

   Any one of the following shall be submitted as proof of business name registration (in pdf):

   a. For single proprietorship, the Certificate of Business Registration and FDA-regulated activity issued by the Department of Trade and Industry (DTI);

   b. For Corporation, Partnership and other Juridical Person, the Certificate of Incorporation or License to transact business in the Philippines issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation/Partnership shall specify the activity relating to health product/s (e.g. manufacturing, distribution [importation, exportation, wholesaling], retail selling in case of pharmaceutical products or medical devices) applied for shall be reflected in the primary or secondary purposes;

   c. For Cooperative, the Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or

   d. For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter or other requirements, deemed suppletory to the application.

Note: *When the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit/Mayor's Permit, or Barangay Certificate with complete business address.*

If the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.

*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, latest audited Financial Statement with Balance Sheet (in pdf). For those that have no Financial Statement (FS) yet, Statement/Certification of Initial Capitalization (in pdf) signed by the owner or accountant.

   The submitted documents shall be subject to validation by FDA during inspection and validity of the LTO. Any findings of under declaration shall be considered as misrepresentation and be a ground for regulatory action.

4. **Risk Management Plan (RMP)** for the following establishments:

   a. Manufacturers of foods, drugs, medical devices, health-related devices such as equipment or devices used for treating sharps, pathological, and infectious wastes, and water purification treatment devices and/or systems, cosmetics, and household urban hazardous substances (HUHS) including household/urban pesticides (HUPs) and toys and childcare articles (TCCAs);

   b. Traders and Distributors (importers, exporters, and/or wholesalers) of foods, drugs, medical devices, health-related devices such as equipment or devices used for treating sharps, pathological, and infectious wastes, and water purification treatment devices and/or systems, cosmetics, and HUHS including HUPs and TCCAs;

   c. Drug Pharmaceutical outlets including Drugstores, Contract Research Organizations, and Sponsors;

   A copy of RMP from the above-mentioned applicant shall also be presented during inspections including that of Medical Device Retailers.

5. **Site Master File (SMF)** for the following establishments:

   Manufacturers including packers and repackers of foods, pharmaceutical products, medical devices, health-related devices such as equipment or devices used for treating sharps, pathological, and infectious wastes, and water purification treatment devices and/or systems, cosmetics, and HUHS including HUPs and TCCAs;

   For Drug Manufacturers, the SMF to be submitted shall follow the PIC/s PE 008-04 Explanatory Notes Pharmaceutical Manufacturers On the Preparation of a Site Master File and its Revisions.

   A copy of the SMF shall also be presented by the applicant during inspections.

6. **List of Sources and Authorized Suppliers/Clients for Manufacturers including Packers/Repackers, Traders, and Distributors (Importers, Exporters, Wholesalers)**

Contract of Agreement – For appropriate determination of activity that shall be indicated in the LTO, a copy of the Contract of Agreement is recommended to be submitted. The basis for the LTO activity shall depend on the legally binding contract agreement between the establishment and its client/supplier.

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

Copy(ies) of the Contract of Agreement(s) of the applicant shall be presented during inspections.

7. Payment of appropriate fees.

B. REQUIREMENTS FOR REGULAR RENEWAL LICENSE TO OPERATE APPLICATION

1. Accomplished eApplication Form through the FDA eServices Portal System

Among other information, the applicant shall provide the following information:

a. License Number and its validity date;

b. Security code as provided in the QR Code of current LTO Certificate, or a sequence number located at the bottom right corner of the LTO Certificate;

c. Contact Information

2. For MSMEs, latest audited Financial Statement with Balance Sheet (in pdf). For those that have no Financial Statement (FS) yet, Statement/Certification of Initial Capitalization (in pdf) signed by the owner or accountant.

   The submitted documents shall be subject to validation by FDA during inspection and validity of the LTO. Any findings of under declaration shall be considered as misrepresentation and be a ground for regulatory action.

3. 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 AUTOMATIC RENEWAL LICENSE TO OPERATE APPLICATION

1. Accomplished eApplication Form through the FDA eServices Portal System

   Among other information, the applicant shall provide the following information:

   a. License Number and its validity date;

   b. Security code as provided in the QR Code of current LTO Certificate, or a sequence number located at the bottom right corner of the LTO Certificate;

c. Contact Information

2. The application is filed before the expiration date of the license;

3. The prescribed renewal fee is paid upon filing of the application; and

4. A sworn statement (Declaration and Undertaking) indicating no change or variation whatsoever in the establishment is attached to the application.

D. 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

Non-submission of the above requirements shall be a ground for the disapproval of the application.

ANNEX C

QUALIFIED PERSON QUALIFICATIONS AND CREDENTIAL REQUIREMENTS

Type of Establishment	Qualified Person	Qualification/Requirement
CDRR Drug Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter), pharmaceutical outlet, and RONPD	Licensed and Registered Pharmacists (RA No. 10918)	a. Professional Regulation Commission (PRC) Identification Card (ID); b. Certificate of Completion issued by the FDA or other training institutions, seminar/training certificate on drug safety, quality, and efficacy and other applicable trainings, Basic and Advance Course on Good Clinical Practice for CROs/ sponsors. Such training or seminar must have been conducted not more than two (2) years reckoned from the date of submission of application for LTO; and c. Proof of termination of employment if previously connected with another pharmacy/establishments.
Contract Research Organizations (CROs) and Sponsors		
Veterinary Establishments a. Retailers	a. Licensed and Registered Pharmacist or Doctor of Veterinary Medicine (RA 9268)	
b. Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter)	b. Licensed and Registered Pharmacists (RA No. 10918)	
CFRR Food Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter)	**For small, medium, large FBOs:** PRC-registered for the following courses: food technology, food and nutrition, chemistry, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture; or certification for microbiology and other food-related courses not requiring PRC registration.	a. Graduate of food technology, food and nutrition, chemistry, chemical engineering, veterinary medicine, fisheries, agriculture; or certification for microbiology and other food-related courses b. Valid PRC ID c. Seminar/training certificate on food safety, GMP, HACCP, and other food safety related regulations given by the DOH-FDA, or FDA recognized government institutions, the academe, professional associations,

		and third-party service providers conducted within 2 years from the date of filing of application. Both the academic and training requirements shall be satisfied.
	For micro FBOs: Graduate of the following courses: food technology, food and nutrition, chemistry, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture and other food-related-courses	a. Certified true copy of Diploma; and b. Seminar/training certificate on food safety, GMP, HACCP, and/or other food safety related regulations given by the DOH-FDA, or FDA recognized government institutions, the academe, professional associations, and third-party service providers conducted within 2 years from the date of filing of application.
CDRRHR Retailers of ophthalmic lenses, prisms, contact lenses and their accessories and solutions, low vision aids, and similar appliances and devices wherein the dispensing is governed by RA 8050 or the "Revised Optometry Law of 1995".	Registered professional or graduate of allied health courses including but not limited to Optometry, Doctor of Medicine, Pharmacy, and vocational course or other courses relevant to the medical devices being handled.	At least graduate of vocational courses and profession with or without Board/Licensure examination relevant to the medical device being handled: a. PRC ID for professions with Board/Licensure examination; b. Diploma or Certificate (e.g., TESDA, Other government or private accredited training providers) for vocational courses relevant to the medical device being handled; or c. Diploma for profession without Board/Licensure Examination
Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) of health-related devices specifically:	Graduate of engineering courses preferably chemical, sanitary, civil, and mechanical, or other science courses relevant to the device to be distributed	a. PRC ID for professions with Board/Licensure examination; or

a. Equipment or devices used for treating sharps, pathological and infectious wastes; and b. Water purification treatment devices and/or systems		b. Diploma for profession without Board/Licensure Examination
Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) and Retailer of medical devices	a. Registered professional or graduates in the field of health profession such as Pharmacy, Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Physical Therapy, and other allied science courses relevant to the device to be distributed. b. Engineering profession that includes but not limited to EE, ECE, ME, CoE, CHE, SE, Computer Science, and Chemistry	a. Certificate of Attendance to seminars, training, learning and development activities on device safety, quality and use given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organization which includes the WHO and ISO; and b. PRC ID for professions with Board/Licensure exam or Diploma for profession without Board/Licensure exam.
CCHUHSRR Manufacturer of Cosmetic establishments	Registered Chemist, Chemical Engineer, or Pharmacist	a. Valid PRC ID b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on cosmetic safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organization.
Trader and Distributor (Wholesaler, Importer, Exporter) of Cosmetic establishments	Registered professional or graduates in the field of allied health, chemistry, chemical engineering, or cosmetic science with verifiable, recognized, and updated trainings on the safety, quality, and use of cosmetics	a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and b. Certificate and copy of program of activities as proof of attendance to seminars,

		trainings, learning and development activities on cosmetic safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations.
• Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) Household/Urban Hazardous Substances	**For HUHS** - Registered professional or graduates in the field of allied health, chemistry, or chemical engineering with verifiable, recognized, and updated trainings on the safety, quality, and use of HUHS	a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on HUHS safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations.
	For HUP - Registered professional or graduates of Pharmacy, Chemistry, Chemical Engineering, Toxicology, Veterinary Medicine, Agricultural Biotechnology (Entomology) and Entomology	a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on HUP safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations.
	For TCCA - Bachelor's degree with verifiable, recognized, and	a. Valid PRC ID for professions with board/licensure exam or Diploma for professions

	updated trainings on the safety, quality, and use of TCCA	without board/licensure exam; and b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on TCCA, safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations.

ANNEX D

LIST OF REQUIREMENTS FOR SPECIFIC VARIATION IN THE LTO

A. Major Variation

Type of Variation	Requirement
Transfer of Location of Manufacturing/Packing/Repacking Plant, Medical Device/Drug Retailer Physical transfer of the establishment (and may entail changes in the previously approved address)	1. Application Form; 2. Payment of appropriate fees; 3. Proof of business address reflecting the new plant location: and **a. For Single Proprietorship** Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location **b. For SEC-registered establishments** i. Amended Articles of Incorporation (if transferred from one city/municipality/province); or ii. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality) If the establishment address is different from the address indicated in the SEC Registration, provide Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new plant location or PEZA certificate, if applicable ***If the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.*** 4. Updated Site Master File
Expansion/Reduction of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity	1. Application Form; 2. Payment of appropriate fees; and

1. Expansion shall refer to expansion made to the existing location of the establishment. 2. Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, parametric, etc.) 3. Change in manufacturing activity shall refer to an addition/deletion of activity that a manufacturer engages in (e.g., LTO as Manufacturer-Repacker to Manufacturer-Packer)	3. Updated Site Master File (including previous and expanded floor plan) For pharmaceutical and food products, satisfactory laboratory analysis of not more than one (1) year from the issuance shall also be presented.
Transfer/Addition/Deletion of Warehouse handling, pharmaceutical, food, cosmetic, household/urban hazardous substances, and medical device products Physical transfer and addition of the warehouse of the establishment	1. Application Form; 2. Payment of appropriate fees; and 3. Business permit reflecting new warehouse; ***In case of transfer or addition, if the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.***
Additional Drugstore Activities	1. Application Form; 2. Payment of appropriate fees; and 3. Other documents related or specific to the additional activity, such as but not limited to: **a. Adult vaccination** i. Standard Operating Procedure (SOP) for the cold chain management following FDA Circular 2021-003 (Revised Guidelines on the Cold Chain Management for Pharmaceutical Products and Establishments);

	ii. SOP for the vaccination/ immunization activities; and iii. Certification as a Certified Immunizing Pharmacist **b. Dispense Vaccines and Biologicals** SOP and compliance with the requirements for the cold chain management following FDA Circular 2021-003 and its amendment or revision, and the applicable rules on GDSP. **c. Online Ordering and Delivery** i. SOP for the online ordering and delivery activities; ii. Official Website link of the Drugstore; and iii. Website screenshot showing the ordering system and the placement of LTO details **d. Compounding of pharmaceutical products not categorized as sterile or non-sterile complex pharmaceutical product** SOP for the compounding activities. **Note: For Sterile and Non-Sterile Complex pharmaceutical products the rule on GMP Compliance shall apply* NOTE: The establishment shall be inspected for GMP clearance prior approval of the variation.

B. Minor Variation

Transfer of Location of Offices (Not considered as Manufacturing Plant or Medical Device/Drug Retailer) Physical transfer of the office of the establishment	1. Application Form; 2. Payment of appropriate fees; 3. **Proof of business address reflecting the new office location:** **a. For Single Proprietorship** Business Permit/Mayor's Permit or Barangay Business

	Permit/Clearance reflecting the new office location **b. For SEC-registered establishments** i. Amended Articles of Incorporation (if transferred from one city/municipality/province); or ii. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality) 4. PEZA Certificate reflecting the new office address, if applicable; and 5. Notarized Contract of Lease or any proof of ownership of the new office location, if applicable If the establishment address is different from the address indicated in the SEC Registration, provide Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location.
Expansion/extension of Office Establishments and Medical Device/Drug Retailer In case of office establishments, it shall refer to area expansion made to the existing location of the establishment within the same building. In case of Medical Device/Drug Retailer, it shall refer to area expansion made to the existing location only.	1. Application Form; 2. Payment of appropriate fees; 3. Current floor plan; and 4. Expansion floor plan
Change in ownership of the establishment	1. Application Form; 2. Payment of appropriate fees; 3. Business name registration reflecting new ownership; and

	4. Proof of the transfer of ownership such as any of the following: a. Deed of Sale or Assignment or Transfer of Rights/Ownership; b. Memorandum of Agreement (MOA); or c. Notarized Affidavit: i. Previous owner, chairman or CEO (covered by appropriate board resolution) of the previously licensed establishment validating the transfer; or ii. In case of transfer to heirs due to death of previous owner, affidavit of the authorized heir
Change in the business name of the establishment	1. Application Form; 2. Payment of appropriate fees; and 3. Business name registration reflecting the new business name
Change of Distributor Activity Shall refer to an addition in/deletion of/change activity that the distributor previously engaged in.	1. Application Form; 2. Payment of appropriate fees; and 3. Appropriate Contract Agreements showing change in activity
Zonal Change in Address Change of the name/number of the street/building without physical transfer of the establishment	1. Application Form; 2. Payment of appropriate fees; and 3. Certificate of Zonal Change from the Local Government Unit or Business Permit/Mayor's Permit/Barangay Clearance stating that there is no actual transfer of the establishment
Addition or Change of Qualified Person (QP) for Establishments under CCHUHSRR and FBOs	1. Application Form; 2. Payment of appropriate fees; 3. Valid PRC ID, if applicable; and

Addition or change in the identified qualified person initially registered with the FDA	4. Applicable requirements as specified in Annex C
Addition or Change of Pharmacist for Pharmaceutical/Veterinary Doctor for Pharmaceutical Establishment and Qualified Person for Medical Device Establishment **Addition or Change of Optometrist for Medical Device Optical Product-Dispensing Establishment**	1. Application Form; 2. Payment of appropriate fees; 3. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and 4. **For Pharmaceutical Establishment:** Proof of termination of employment/resignation of the additional/new pharmacist, if previously connected with another establishment except for cases of activities involving pharmaceutical products covered by Section 31.b of RA No. 10918; 5. **For Optometrist and Qualified Person of Medical Device Establishment:** Proof of termination of employment/resignation of additional/new optometrist or Qualified Person if previously connected with another establishment; 6. For Pharmacists handling Category A and B, list of all outlets including Name of Establishment, Address, plotted Geolocation, Day, and Time of shift and LTO number.
Change on the Details of Qualified Person/Pharmacist/Optometrist Updates/changes, but not limited to the following: 1. Validity of the government-issued ID 2. Change and/or corrections in the details of the submitted government-issued ID (e.g., marital status, print errors)	1. Application Form; 2. Payment of appropriate fees; 3. For profession with board exam: PRC ID (back-to-back) with signature at the back panel of the ID; 4. For non-board: Valid government-issued ID (e.g., passport, driver's license, SSS, etc.); and 5. Other evidence corresponding to the update/change not mentioned

Change of Authorized Person Change in the authorized person initially registered with the FDA	1. Application Form; 2. Payment of appropriate fees; and 3. Valid government issued ID
Addition or Deletion of Medical Device Retailer Activity such as but not be limited to the following: 1. Retail stores for medical devices; 2. Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System; 3. Sellers using online shopping website, social media platforms and/or TV shopping companies in selling or offering to sell medical device directly to the general public; 4. Operator of medical device vending machine; 5. Optical shops; and 6. Pharmaceutical outlets, such as drugstores, or boticas, and retail outlets for non-prescription drugs (RONPD) that also sell or offer to sell medical device	1. Application Form; and 2. Payment of appropriate fees
Change of official e-mail address of the establishment	1. Application Form; 2. Payment of appropriate fees; and 3. Request Letter signed by the owner/CEO/President
Addition/Deletion of Sources and Products for medical device, household/urban hazardous substances, cosmetic, and pharmaceutical establishments	1. Application Form; and 2. Payment of appropriate fees

Addition/deletion of source(s) and product(s) in the previous/existing list *Note:* Notarized Valid Contract Agreement; or For foreign source(s), a copy of the contract agreement duly authenticated by the host government of the country of origin (legalized by the Philippine Embassy/Consulate if from a non-Apostille country shall be available during inspection of the establishments.	

ANNEX E

LICENSE TO OPERATE APPLICATIONS EXEMPTED FROM AUTOMATIC RENEWAL

The automatic renewal applications shall not be applicable in the following instances:

1. Those with critical findings of inspection during the validity of the LTO immediately preceding the renewal application, even if with accepted Corrective and Preventive Action (CAPA);

2. Those establishments that were not inspected at all during the validity of the LTO immediately preceding the renewal application;

3. Those renewal application with pending variation or expired LTO at the time of application;

   Note: Pending variation or expired LTO are also not qualified in regular renewal application.

4. Those with written directive from the Office of the Director General for deferment of action for renewal applications or with penalty of fine not yet settled or whose license has been suspended or revoked; and

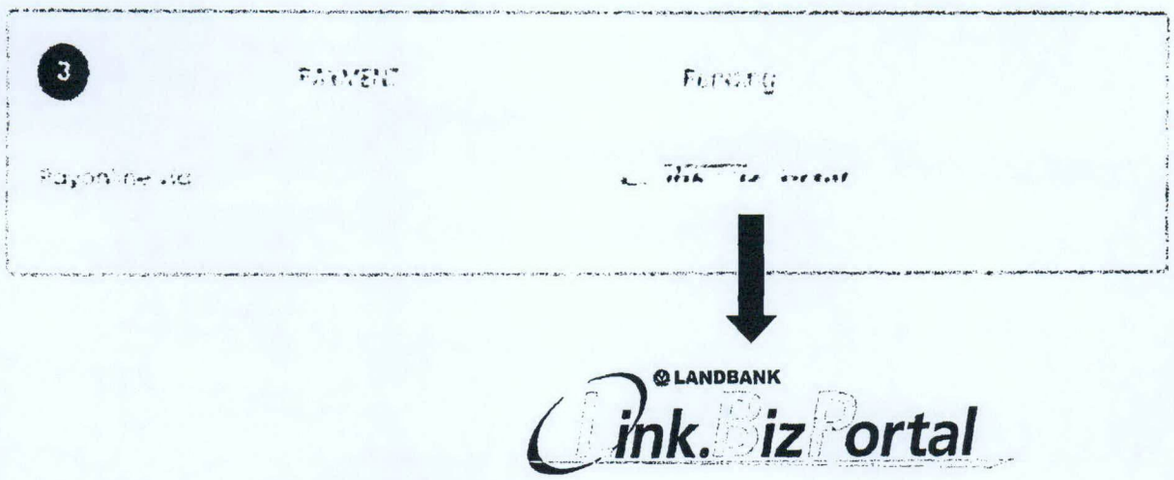
5. Such other analogous instances as determined by the FDA.

ANNEX F

FDA APPLICATION PAYMENT PROCEDURE THROUGH THE eSERVICES PORTAL SYSTEM

I. PAYMENT PROCEDURE THROUGH THE LINK.BIZ INTEGRATED

A. In the Application status, under "Payment", the applicant shall click on the Land Bank Link.biz Portal Logo.



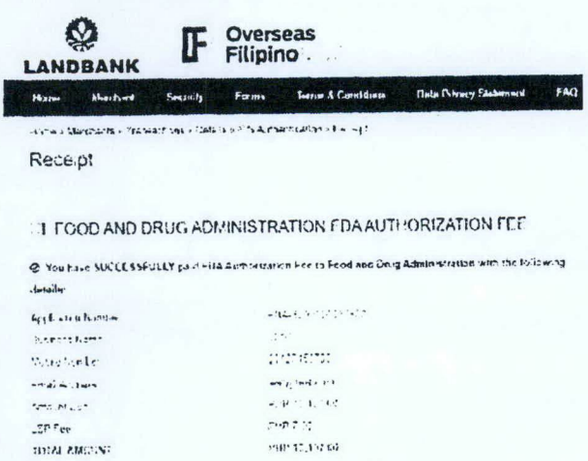
B. The applicant shall be redirected to the Land Bank Link.Biz Portal Page. The details of the application including the amount to be paid is/are automatically filled.

C. The applicant shall fill out the online transaction form.

D. Choose the **Payment Mode** in the drop-down menu and fill in the required information.

E. Click the check box to agree with the Terms and Conditions.

F. Upon successful payment, a receipt (as shown below) shall appear.



G. The FDA eServices Portal System shall be prompted upon the online issuance of receipt. Thereafter, the payment shall be indicated under the "Timestamp" column.

H. Upon successful payment, the application shall automatically deck to the next application process.

ANNEX G

RULES ON RENEWAL APPLICATION FEES AND SURCHARGES

1. If the applicant fails to pay the corresponding renewal fee less the pre-assessment fee as prescribed in the Order of Payment within the validity of the License to Operate, the following shall apply:

   a. Disapproval of renewal application;
   b. Forfeiture of pre-assessment fee;
   c. Apply for a new renewal application;
   d. New renewal application shall pass through another pre-assessment process after payment of pre-assessment fee; and
   e. First-in-first-out applies

2. If the validity of the LTO is less than ten (10) working days, the validity of the Order of Payment shall follow the remaining validity of the LTO. If the applicant fails to pay the corresponding renewal fee less the pre-assessment fee, the rule in number 1 above applies, but with addition of imposition of the corresponding surcharge.

3. If the date of issue of the Order of Payment falls within the expiry date of the license, the applicant shall pay within such day. Failure of which, the rule in number 2 above applies.

4. If the validity of the Order of Payment is within the surcharge period but within the first one (1) month expiration date, ten (10) percent of the renewal fee in addition to twice the amount of renewal fee as surcharge applies.

5. If the one (1) month surcharge period is less than ten (10) working days, the validity of the Order of Payment shall follow the remaining validity of the first month.

   If the applicant fails to pay the corresponding renewal fee plus the surcharge, rule number 1 above applies, but with addition of imposition of twenty (20) percent of the renewal fee in addition to twice the amount of the renewal fee.

6. If the validity of the Order of Payment is within the surcharge period but within the second (2nd) month expiration date, twenty (20) percent of the renewal fee in addition to twice the amount of renewal fee as surcharge applies.

   If the applicant fails to pay the corresponding renewal fee plus the surcharge, rule number 1 above applies, but with addition of imposition of thirty (30) percent of the renewal fee in addition to twice the amount of the renewal fee.

7. If the validity of the Order of Payment is within the surcharge period but within the third (3rd) month expiration date, thirty (30) percent of the renewal fee in addition to twice the amount of renewal fee as surcharge applies.

If the applicant fails to pay the corresponding renewal fee plus the surcharge, rule number 1 above applies, but with addition of imposition of forty (40) percent of the renewal fee in addition to twice the amount of the renewal fee.

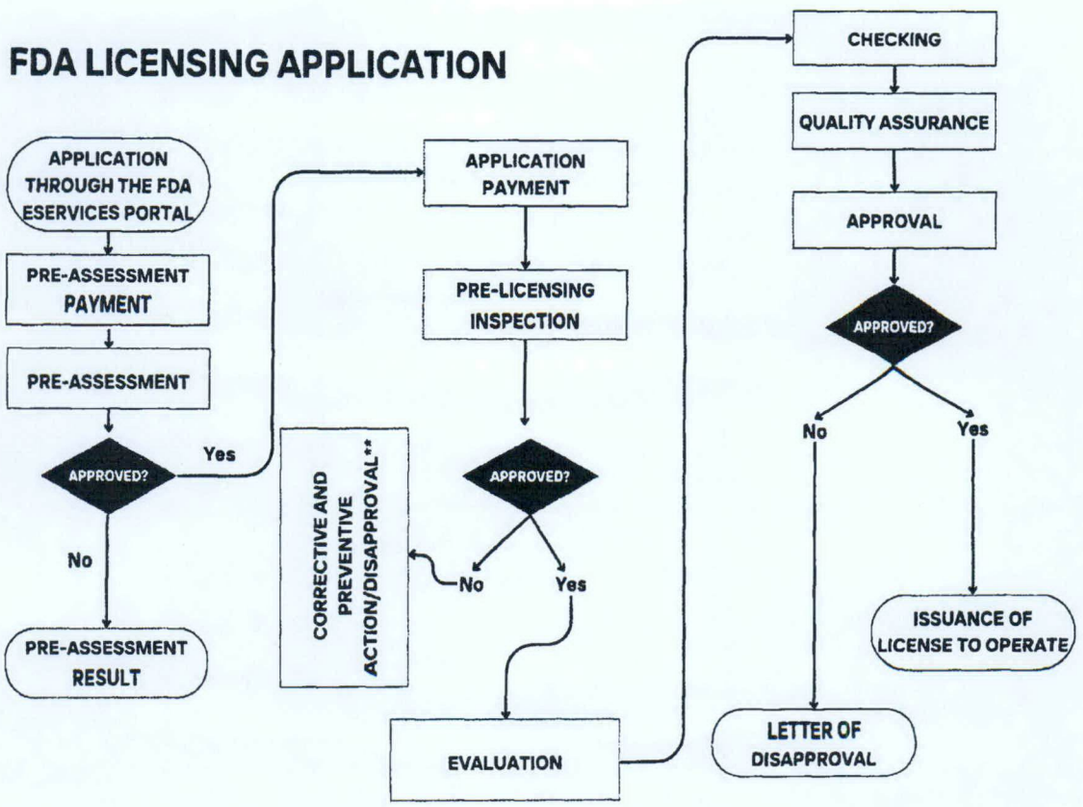
8. If the validity of the Order of Payment is within the surcharge period but within the fourth (4th) month expiration date, forty (40) percent of the renewal fee in addition to twice the amount of renewal fee as surcharge applies.

   If the applicant fails to pay the renewal fee plus the surcharges, the following rules shall apply:

   a. the application shall be considered expired;
   b. the initial pre-assessment fee shall be forfeited;
   c. the application shall undergo the initial filing, inspection, and evaluation procedure; and
   d. the application shall be subject to the total surcharge or penalty equivalent to twice the renewal fee plus forty percent of the renewal fee plus the amount of initial filing fee.

ANNEX H

LICENSE TO OPERATE PROCESS FLOW*



Note: **The above FDA Licensing Application Process Diagram only presents the general process flow for License to Operate. The details shall adhere to the provisions set forth in the Administrative Order.*

*** Corrective and Preventive Action/Disapproval decision shall depend on the actual FDA inspection findings on the establishment. Any recommendation for disapproval shall be forwarded for further evaluation and issuance of letter of disapproval.*