



## NOTICE OF PUBLIC CONSULTATION

The Food and Drug Administration (FDA) is mandated to issue standards and appropriate marketing authorizations (MAs) to all its covered establishments, facilities, and health products. Through this endeavor, the FDA streamlined its processes through the establishment of various online application platforms for the issuance of MAs including License to Operate (LTO) for Manufacturers, Distributors, Traders, Drug Outlets, Retailers, Clinical Research Organizations, and other health establishments as determined by the FDA. Relative to this, the FDA drafted an Administrative Order entitled, **“Updated Guidelines on the Application for License to Operate of Health Product Establishments with the Food and Drug Administration”** which aim to reengineer and automate the FDA’s processes for initial, renewal, and variation of LTO.

In the interest of service and to seek the inputs of stakeholders that will be affected by the above-mentioned proposed policy, the FDA is respectfully inviting **one (1) representative of each company/ organization from the health industry** to attend the **Public Hearing to be scheduled on the following dates at the FDA Conference Hall, Civic Drive, Filinvest, Alabang, Muntinlupa City:**

Target Participant	Type of Health Product	FDA Resource Speaker	Date/Time
<ol style="list-style-type: none"> <li>1. Manufacturer</li> <li>2. Trader</li> <li>3. Distributor (Wholesaler, Importer, Exporter)</li> <li>4. Drug Outlets <ul style="list-style-type: none"> <li>- Drugstores</li> <li>- Pharmacies</li> <li>- Retail Outlet for Non-Prescription Drugs</li> </ul> </li> <li>5. Clinical Research Organizations and Sponsors</li> </ol>	<ul style="list-style-type: none"> <li>• Drug products for human use</li> <li>• Biological drug products</li> <li>• Radiopharmaceuticals and precursors</li> <li>• Advance therapy drug products</li> <li>• Homeopathic products</li> <li>• Medical gases</li> <li>• Herbal and traditional medicines</li> <li>• Orphan drugs</li> <li>• Animal health products</li> <li>• Other drug products</li> </ul>	<b>CDRR &amp; FDA INSPECTORATE</b>	<b>04 July 2023 9:00 AM – 12:00 PM Tuesday</b>
<ol style="list-style-type: none"> <li>1. Manufacturer</li> <li>2. Trader</li> <li>3. Distributor (Wholesaler,</li> </ol>	<ul style="list-style-type: none"> <li>• Medical devices</li> <li>• Radiation-emitting devices</li> <li>• In-vitro diagnostic devices and reagents</li> </ul>	<b>CDRRHR &amp; FDA INSPECTORATE</b>	<b>04 July 2023 1:30 PM – 4:30 PM Tuesday</b>



Importer, Exporter) 4. Retailers of Medical Devices	<ul style="list-style-type: none"> <li>• Refurbished medical devices</li> <li>• Custom-made medical devices</li> <li>• Equipment or devices used for treating sharps, pathological, and infectious wastes</li> <li>• Water treatment devices/systems</li> <li>• Other health-related devices</li> </ul>		
1. Manufacturer 2. Trader 3. Distributor (Wholesaler, Importer, Exporter)	<ul style="list-style-type: none"> <li>• Cosmetic products</li> <li>• Household/urban pesticides</li> <li>• Toys and childcare articles</li> <li>• Other cosmetic products</li> </ul>	<b>CCHUHSRR &amp;          FDA          INSPECTORATE</b>	<b>05 July 2023          9:00 AM –          12:00 PM          Wednesday</b>
1. Manufacturer 2. Trader 3. Distributor (Wholesaler, Importer, Exporter)	<ul style="list-style-type: none"> <li>• Processed food products</li> <li>• Food/dietary supplements</li> <li>• Raw materials, ingredients, and additives for food</li> <li>• Other food products</li> </ul>	<b>CFRR &amp; FDA          INSPECTORATE</b>	<b>05 July 2023          1:30 PM –          4:30 PM          Wednesday</b>
1. <b>Micro, Small, and          Medium          Enterprises</b> 2. Industry Associations 3. Government- Agencies 4. Concerned/Interest Groups 5. Other identified stakeholders			

The Public Consultation is **on a first-come, first-served basis** and we have allotted **fifty (50) slots in each schedule**. The FDA will restrict the registration link access once we already receive the allotted number of participants to attend the public consultation. Registration is through this link: <https://forms.office.com/r/NUSx0U7cNy> .

For those who are not registered, you may send an e-mail to the FDA-Policy and Planning Service at [pfpid@fda.gov.ph](mailto:pfpid@fda.gov.ph) signifying your interest to participate by following the below subject title:

“FDA-LTO PUBCON [*Name of Organization/Company/Association/Government Agency*]  
 [*FDA-CONCERNED CENTER (e.g. CDRRHR)*]”

Further, provided herewith a copy of the draft Administrative Order. You may provide the comments prior the scheduled public consultation and send it to [pfpid@fda.gov.ph](mailto:pfpid@fda.gov.ph) not later than 30 June 2023.

Thank you very much.





Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

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3 **ADMINISTRATIVE ORDER**

4 No. \_\_\_\_\_

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6 **SUBJECT: Updated Guidelines on the Application for License to Operate of**  
7 **Health Product Establishments with the Food and Drug**  
8 **Administration**  
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11 **I. RATIONALE**

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13 Republic Act (RA) No. 9711, otherwise known as the “Food and Drug Administration  
14 (FDA) Act of 2009” mandates the FDA to establish and maintain an effective health regulatory  
15 system to promote the safety, quality, and efficacy of health products. Pursuant to the  
16 mentioned, the FDA, as one of the regulatory arms of the Department of Health (DOH), is  
17 mandated to issue standards and appropriate authorizations that cover establishments, facilities,  
18 and health products under its jurisdiction. Such endeavor shall be visible in its regulation of  
19 Manufacturers, Traders, and Distributors (Importers, Exporters, and Wholesalers), among  
20 others, engaged in business and operations involving health products prior to manufacture,  
21 importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use,  
22 promotion, advertising, or sponsorship activities.  
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24 In 2018, RA No. 11032, otherwise known as the “Ease of Doing Business and Efficient  
25 Government Service Delivery Act” was issued, which aids in the promotion of streamlined and  
26 simplified transactions in the government. Hence, the FDA, congruent with RA 11032,  
27 established unified licensing guidelines to adopt a more harmonized licensing system across  
28 all health products under its jurisdiction through the issuance of Administrative Order (AO)  
29 No. 2020-0017, otherwise known as the “Revised Guidelines on the Unified Licensing  
30 Requirements and Procedures of the FDA Repealing AO No. 2016-0003”.  
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32 The implementation of AO No. 2020-0017, in parallel with the digitalization initiatives  
33 of the FDA, promotes a harmonized licensing application that encompasses all types of covered  
34 health products. While it is notably used, certain requirements that need to be complied with  
35 by the regulated entities are not given due emphasis in the implemented AO. These  
36 requirements are necessary for the evaluation of technical compliance and inspection of  
37 covered health product establishments.  
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39 Further, the compliance of the FDA with international standards shall be evident in its  
40 national regulatory systems with the use of benchmarking methodology as provided by the  
41 World Health Organization – Global Benchmarking Tool (WHO-GBT). This shall help the  
42 FDA in the self-evaluation of its processes towards reaching a level of a more strengthened  
43 regulatory oversight.  
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45 Hence, in the pursuit of achieving an updated regulatory system and aligning with the  
46 mentioned policies, this Administrative Order is hereby issued.  
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50 **II. OBJECTIVES**

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52 The objectives for issuing this Administrative Order are as follows:

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- 54 1. To further reengineer the FDA’s processes and automate its system for initial, renewal, and  
55 variation applications for License to Operate (LTO) through the FDA available online  
56 application platforms; and  
57 2. To update the list of documentary requirements for LTO applications, in addition to other  
58 technical requirements that shall be presented during the inspection of the FDA-covered  
59 establishments.

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62 **III. SCOPE**

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

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- 67 1. Manufacturers, including Packers/Repackers;  
68 2. Refurbishers of medical devices;  
69 3. Traders;  
70 4. Distributors as Importers, Exporters, and/or Wholesalers;  
71 5. Drug outlets, such as drugstores, pharmacies (community, or institutional); or  
72 *boticas*, and retail outlets for non-prescription drugs (RONPDs);  
73 6. Retailers of Medical Devices  
74 7. Clinical Research Organizations (CROs) and Sponsors

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

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- 78 1. Under the CCHUHSRR, all cosmetic products, household/urban hazardous  
79 substances (HUHS), including household/urban pesticides, and toys and childcare  
80 articles;  
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82 2. Under the CDRR, all drugs, including but not limited to drug products for human  
83 use, biological drug products such as blood products and vaccines,  
84 radiopharmaceuticals and precursors, advance therapy drug products such as  
85 human cells, tissues, and cellular and tissue-based products, homeopathic products,  
86 medical gases, herbal and traditional medicines, orphan drugs, animal health  
87 products, and other drug products as determined by the FDA;  
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89 3. Under the CDRRHR, all medical devices, radiation-emitting devices, in-vitro  
90 diagnostic devices, and reagents; refurbished medical devices; custom-made  
91 medical devices; equipment or devices used for treating sharps, pathological, and  
92 infectious wastes, water treatment devices/systems; and other health-related  
93 devices as determined by the FDA; and  
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95 4. Under the CFRR, all processed food products, food/dietary supplements, raw  
96 materials, ingredients, and additives for food.

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98 This does not preclude the FDA from updating the scope of health products and  
99 establishments that require regulation in accordance with the FDA rules and regulations.

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**IV. EXCLUSION**

- A. The following shall NOT be covered by this Order:
  - 1. Organizers of national and international trade fairs and exhibits;
  - 2. Donors, organizations, or persons involved in donations, medical missions, and other humanitarian activities;
  - 3. Manufacturers, Traders, or Distributors of collector’s items;
  - 4. Retailers of processed food products, cosmetics and household/urban hazardous substances, including household/urban pesticides and toys and childcare articles;
  - 5. Groceries, convenience stores, and supermarkets without wholesale activity for foods, slaughterhouses, or abattoirs, dressing plants, fish ports, wet markets, school canteens; restaurants without importation and manufacturing/repacking activity of prepacked foods; water refilling stations, street food sale including ambulant vending, fast foods, kiosks, caterers, chandlers, and the likes;
  - 6. Institutions and companies that provide vaccinations to their employees; and
  - 7. Facilities covered by the DOH One Stop Shop Licensing System<sup>1</sup>.
  
- B. The licensing of the following establishments or persons shall be governed by separate rules and regulations:
  - 1. Salt Manufacturers, Distributors, and Traders shall follow RA 8172 <sup>2</sup>(ASIN Law) and its revised IRR;
  - 2. Bottled Water Manufacturers shall follow AO No. 18-A s. 1993<sup>3</sup>;
  - 3. Radiation facilities shall follow AO No. 2020-0035<sup>4</sup>
  - 4. Operators of pest control for non-agricultural purposes shall follow DOH AO No. 2019-0010<sup>5</sup>;
  - 5. Applicators of household/urban pesticides and their training providers shall follow DOH AO No. 2019-0010; and
  - 6. Tobacco Manufacturers and Distributors including Importers

**V. DEFINITION OF TERMS**

For the purpose of implementing this Order, all the identified terms used herein shall have the meaning as defined in RA 9711, its IRR, and related laws and regulations. The following terms or words and phrases shall mean or be understood as follows:

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

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<sup>1</sup> A strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other health facilities.  
<sup>2</sup> An Act Promoting Salt Iodization Nationwide (ASIN)  
<sup>3</sup> Standards of Quality and Requirements for the Processing, Packaging, and Labelling of Bottled Drinking Water  
<sup>4</sup> Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorization  
<sup>5</sup> Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of their Training Providers

- 143 **B. Contract Research Organization (CRO)** – refers to a person or an organization  
144 (commercial, academic, or other) contracted by the sponsor to perform one or more of  
145 a sponsor’s trial-related duties and functions (ICH GCP 1.20).  
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- 147 **C. Cosmetic/HUHS Manufacturer/Refiller** – a licensed Cosmetic and/or HUHS  
148 establishment engaged in the refilling of bulk cosmetic and/or HUHS products into  
149 smaller quantities in a separate container, which may include labeling and stickering,  
150 with the end view of sale of the product directly to the general public.  
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- 152 **D. Custom-Made Medical Device** – refers to any device specifically made in accordance  
153 with a duly qualified medical practitioner’s written prescription which gives, under his  
154 responsibility, specific design characteristics and is intended for the sole use of a  
155 particular patient. For the purpose of clarity, mass produced devices which need to be  
156 adapted to meet the specific requirements of the medical practitioner or any other  
157 professional user shall not be considered to be custom-made medical devices.  
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- 159 **E. Distributor/Exporter** - refers to any establishment that exports raw materials, active  
160 ingredients and finished products for distribution to other establishments outside the  
161 country.  
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- 163 **F. Distributor/Importer** – refers to any establishment that imports raw materials, active  
164 ingredients and/or finished products for wholesale distribution to other local FDA-  
165 licensed establishments.  
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- 167 **G. Distributor/Wholesaler** - refers to any establishment that procures raw materials,  
168 active ingredients and/or finished products from local FDA-licensed establishments  
169 for local distribution on a wholesale basis.  
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- 171 **H. Health-related device** – means any device not used in health care but has been  
172 determined by the FDA to adversely affect the health of the people.  
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- 174 **I. Initial Application** - refers to the type of LTO application submitted to the FDA prior  
175 to engaging in the business or operation involving the manufacture, importation,  
176 exportation, sale, offer for sale, distribution, transfer, and where applicable the use,  
177 testing, promotion, advertisement, and/or sponsorship of health products.  
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- 179 **J. Major Variation** - covers changes in the operations of the establishment that may  
180 affect significantly and/or directly the aspects of safety and quality and when  
181 applicable, efficacy of the products.  
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- 183 **K. Manufacturer** - refers to any establishment engaged in any and all operations  
184 involved in the production of health products including preparation, processing,  
185 compounding, formulating, filling, packing, repacking, altering, ornamenting,  
186 finishing, and labeling with the end in view of its storage, sale, or distribution:  
187 Provided, that the term shall not apply to the compounding and filling of prescriptions  
188 in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.  
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- 190 **L. Minor Variation** - covers changes in administrative matters and/or changes in the  
191 operations of the establishments but with minimal impact on the safety, quality, and  
192 when applicable, efficacy of the products.

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- M. 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.
- N. Pre-licensing Inspection** – refers to an inspection performed prior to the approval of a new 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 FDA existing regulations.
- O. Qualified Person (QP)** - refers to an organic or full-time employee of the establishment who possesses technical competence related to the establishment’s activities and health products by virtue of his profession, training, or experience. A qualified person has the responsibility to comply with the technical requirements of the FDA, 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.
- P. Refilling Station** – refers to the branch office of the Cosmetic and/or HUHS Refiller, including outlets; and mall kiosks, where the refilling activity takes place.
- Q. Refurbished Medical Device** - refers to the medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it: a.) stripping into component parts or subassemblies; b.) checking their suitability for reuse; c.) replacement of components/sub-assemblies not suitable for reuse; d.) assembly of the reclaimed and/or replacement components/sub-assemblies; e.) testing of the assembled device against either original or revised release criteria; or f.) identifying an assembled medical device as a refurbished medical device. (ASEAN Medical Device Directive, 2015).
- R. 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.
- S. 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.
- T. Retailer** - refers to any establishment that sells or offers to sell any health product directly to the general public.
- U. 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



243 risk management plan is a requirement for the issuance of the appropriate  
244 authorization.

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246 **V. Routine Inspection** - refers to the general process of physical or remote inspection of  
247 the facility(ies), warehouses, and/or offices of an establishment, which is conducted  
248 by the FDA at any time during the validity of its LTO. A routine inspection is also  
249 referred to as a post-licensing inspection.

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

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

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

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## 267 **VI. GENERAL GUIDELINES**

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269 **A.** All covered establishments, whether public or private entities, engaged in business or  
270 operation on health products shall first secure an LTO issued by the FDA and, when  
271 applicable, product market authorizations, i.e., Certificate of Product Registration  
272 (CPR), Certificate of Product Notification (CPN), before engaging in any FDA  
273 regulated transactions involving health products.

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

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281 **C.** Establishments shall comply with the applicable standards, including but not limited  
282 to Good Manufacturing Practices (GMP), Good Laboratory Practices, Good Clinical  
283 Practices (GCP), Good Distribution and Storage Practices (GDSP), among others, in  
284 the conduct of their licensing activity(ies).

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286 **D.** In case the health product has been banned or withdrawn for health and safety reasons  
287 in the country of origin, the importer shall immediately undertake the necessary  
288 measures to ban its sale, distribution, or donation, or its immediate recall, withdrawal,  
289 or seizure from the Philippine market.

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- 291 E. Establishments engaged in the sale of health products declared by the FDA to be  
292 injurious, unsafe, or dangerous shall be required to immediately recall, withdraw,  
293 seize, or ban the sale, distribution, or donation to the public.  
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- 295 F. The establishment shall inform the FDA of any changes or variations made to its  
296 license and a corresponding application shall likewise be made for the issuance of an  
297 LTO reflecting the changes or variations made.  
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- 299 G. Manufacturers, Traders, and Distributors shall declare on their application the list of  
300 sources and the respective types and/or name of finished products, semi-finished, raw  
301 materials, active pharmaceutical ingredients, and excipients that are relevant to their  
302 licensed activity.  
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- 304 H. The transfer of location of a manufacturing/packing/repacking plant is considered as  
305 major variation for Manufacturer/Packer/Repacker with an application fee equivalent  
306 to an initial application fee.  
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- 308 I. The FDA shall continue to provide training and seminars. In lieu of FDA sponsored  
309 training and seminars, applicants may submit proof of training from other institutions  
310 offering technical courses relevant to their establishment and activity. Such  
311 certification or documentary evidence of compliance with the required training shall  
312 be sufficient compliance for purposes of application for LTO.  
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- 314 J. To ensure that a tamper-proof security feature is present on all issued LTO certificates,  
315 the FDA shall endeavor to provide a unique Certificate Security Seal to all FDA-issued  
316 LTO. Implementation of the FDA security seal shall be governed by separate rules and  
317 regulations.  
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- 319 K. All provisions stipulated in this Order shall not preclude the FDA from issuing  
320 guidelines relative to specific licensing processes of the covered health product  
321 establishments enumerated under Section III of this Order.  
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## 324 VII. SPECIFIC GUIDELINES

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### 326 A. The following establishments shall comply with the following conditions:

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#### 328 1. For Drug establishments:

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- 330 a. All drug or pharmaceutical establishments based on Section 31 of R.A.  
331 No. 10918 or the Philippine Pharmacy Act, whether public or private,  
332 shall be under the supervision of a registered pharmacist when operating  
333 or open for business, unless otherwise allowed by other pertinent laws  
334 or regulations.
- 335 b. All entities, whether government or non-government, that regularly  
336 procure drugs on wholesale basis from appropriate FDA-duly licensed  
337 drug establishments for distribution to their constituents shall be  
338 required to obtain a license as a drug distributor.
- 339 c. No drug distributors shall sell directly to the general public or consumer  
340 unless they have an LTO as drugstores/retailers.

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- d. All CROs, Sponsors and other concerned entities shall adhere to existing ethical and scientific quality standards of safety and efficacy in the conduct of clinical trials.
  - e. No CRO or Sponsor shall be involved in the conduct of clinical trials without a license from the FDA. Licensed CROs/Sponsors that import/export products subject to clinical trials are no longer required to secure a separate LTO.
  - f. All FDA-licensed drug retailers (drugstore, pharmacy, botica) or RONPD that also offer to sell medical device products shall secure a separate LTO from the FDA as Retailer of Medical Devices;
  - g. All FDA-required information, education, and communication campaign materials shall be displayed in the establishment's conspicuous area.
  - h. All drugstores shall comply with the following:
    - i. Designated 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 health products; and
    - iv. A system for proper safekeeping and maintenance of the records of the specified health products stored at the drugstores, including arrangements to audit the records shall be adequately provided to ensure integrity.

370 **2. For Cosmetic/HUHS establishments:**

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- a. All licensed Cosmetic/HUHS establishments with refilling activity shall only be applied as a Cosmetic/HUHS Manufacturer.
  - b. Specific guidelines on the licensing and inspection of Cosmetic/HUHS Manufacturers/Refillers shall be issued through separate issuances.

377 **3. For Food Business Operators:**

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- a. All establishments shall comply with the current guidelines on general principles of food hygiene including the provisions provided for by Presidential Decree No. 856 on the Code of Sanitation and other general requirements.
  - b. As appropriate, all Food Business Operators (FBOs) shall comply with the relevant standards and requirements of Hazard Analysis Critical Control Point (HACCP), Sanitary Standard Operating Procedures (SSOP), and other good practice regulations and guidelines expounded in Section VI of this AO, to ensure the safety and quality of products.
  - c. LTO is a requirement before a food establishment can join food trade and exhibitions, conduct market research, or test unregistered processed

390 food products. CPR shall be required if the imported product is offered  
391 for sale or for “free tasting” during the food trade and exhibitions.  
392 d. All establishments shall comply with food safety standards recognized  
393 by applicable national regulations or by the Food and Agriculture  
394 Organization of the WHO.  
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396 **4. For Medical Device establishments:**

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- 398 a. The following establishments are considered manufacturers of medical  
399 devices and are required to apply for an LTO:
    - 400 i. All hospitals or establishments engaged in the 3D printing of  
401 medical devices such as ortho, dental, prosthesis, and others  
402 as determined by the FDA;
    - 403 ii. Optical laboratories engaged in the assembly of optical  
404 lenses and frames;
    - 405 iii. Dental laboratories engage in the manufacture of custom-  
406 made dental devices such as dentures, retainers, braces, etc.
  - 407 b. All Distributor-Importer of devices considered “For Research Use  
408 Only” shall secure an LTO from the FDA as medical device  
409 importer/distributor.  
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411 **B. The Qualified Personnel of the establishments shall ensure compliance with the**  
412 **following:**

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- 414 1. All establishments shall have at least one (1) Qualified Person. The QP, upon and  
415 during employment in the establishment, is not and shall not in any way be  
416 connected to, employed by, or engaged with any other FDA-  
417 regulated establishments.  
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- 419 2. A single Qualified Person may be allowed by the FDA to handle a single  
420 establishment with multiple FDA-licensed activities; Provided, that the QP  
421 remains to sufficiently carry out his/her duties and responsibilities as provided in  
422 this Order.  
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- 424 3. The QP shall ensure compliance with FDA procedural guidelines, the prescribed  
425 format and contents of administrative and technical documentary requirements,  
426 timely communications and coordination with the FDA pertaining to regulatory  
427 filings, PMS, pre-licensing inspections and routine inspections, as well as  
428 continuous compliance of his/her affiliated establishment with regulatory  
429 standards, rules, and regulations:  
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- 431 4. The QP shall ensure that all documentary and technical requirements and  
432 information provided in the application, together with all other submissions,  
433 including amendments, are true and correct based on existing records, legal  
434 documents, and other available information.  
435
- 436 5. The QP shall inform the FDA of any changes in the submitted documentary and  
437 technical requirements including the validity of his/her license to ensure that  
438 continuous compliance with the FDA is properly observed at all times.  
439



440 **C. The requirements for applying for LTO shall be as follows:**

441  
442 **1. Initial LTO**

- 443  
444 a. Accomplished eApplication Form with Declaration of Undertaking;  
445 b. Proof of Business Name Registration;  
446 c. Proof of Capitalization for Manufacturers and Traders (Latest Audited  
447 Financial Statement with Balance Sheet or Declaration of  
448 Capitalization);  
449 d. Risk Management Plan;  
450 e. For Manufacturers: Site Master File and Floor Plan; and  
451 f. Payment of Fees

452  
453 **2. Renewal of LTO**

- 454  
455 a. Accomplished eApplication Form with Declaration of Undertaking;  
456 and  
457 b. Payment of Fees

458  
459 **3. Variation**

- 460  
461 a. Accomplished eApplication Form with Declaration of Undertaking;  
462 b. Documentary requirements depending on the variation or  
463 circumstances of the establishment or the product; and  
464 c. Payment of Fees

465  
466 The guidance for the above requirements is attached as Annex A (Requirements for  
467 Initial and Renewal License to Operate Application) and Annex C (List of Requirements for  
468 Specific Variation in the LTO), respectively.

469  
470 **D. Application Process**

- 471  
472 1. All establishments applying for initial, renewal, or variation shall submit their  
473 application through the FDA available online application platforms as guided by  
474 the latest issuances.  
475  
476 2. Applications lodged through the FDA available online application platforms are  
477 the responsibility and accountability of the Owner/President/CEO of an  
478 establishment, as such only the duly authorized personnel of applicant-  
479 establishments and the e-mail address and its password shall be entrusted with such  
480 FDA applications. For emphasis, all consultants, liaison officers, or freelancers  
481 doing business with the establishment or working on a per-product  
482 registration/notification basis shall not be considered duly authorized/qualified  
483 persons.  
484  
485 3. The applicant is expected to agree with the “Declaration of Undertaking” in order  
486 to continue with the application. Such conveys a binding agreement of the  
487 applicant-establishment with the FDA to provide accurate information, affirm  
488 primary responsibility over the products, and comply with all the rules and  
489 regulations set forth during and after the application process. Any

490 misrepresentation of the information in this application shall be subject to  
491 administrative and criminal liabilities, provided by R.A. No. 9711, which includes,  
492 but is not limited to suspension, cancellation, or revocation of the LTO.  
493

- 494 4. All transactions with the FDA shall be communicated to the applicant-  
495 establishment using the registered e-mail address during the initial application. The  
496 declared e-mail address is unalterable, and the FDA shall not be held liable in any  
497 way for loss of access to the official e-mail. If the applicant-establishment wishes  
498 to change the declared e-mail address, the applicant may send a request to the FDA  
499 – Food and Drug Action Center at the provided contact information found on the  
500 FDA’s official website.  
501
- 502 5. Pre-assessment shall be conducted to determine the completeness of the submitted  
503 application. Incomplete submission shall not be accepted, and the application shall  
504 not proceed to the next step of the process.  
505
- 506 6. A successfully pre-assessed application is not equivalent to an approved  
507 application. The evaluation of the correctness and sufficiency of the submitted  
508 documentary requirements with reference to existing administrative and technical  
509 standards, rules, and regulations shall be conducted only during the evaluation and  
510 inspection steps as determined by the FDA.  
511
- 512 7. For applications with complete documentary requirements and posted payment,  
513 the FDA shall issue an Acknowledgement Receipt (AR). An application shall only  
514 be considered filed once the applicant receives the AR from the FDA.  
515
- 516 8. An application for renewal shall be made within three (3) months prior to the  
517 expiration of the validity date of the LTO. Applications filed after the validity date  
518 of the LTO shall be subject to a surcharge as prescribed in R.A. No. 9711 and its  
519 IRR.  
520
- 521 9. The automatic LTO issuance shall only take effect provided the applicant’s  
522 requirements are compliant with the conditions of automatic renewal prescribed  
523 under Republic Act No. 9711 and its IRR including other related FDA issuances.  
524
- 525 10. No application for variation of LTO shall be made and granted when an  
526 establishment has a pending application for renewal of LTO, or vice versa.  
527
- 528 11. Applications filed after the FDA working hours (Monday-Friday; 7:00 AM – 6:00  
529 PM) shall be considered filed on the next working day on a first-in-first-out basis.  
530

#### 531 **D. Payment**

532

- 533 1. Payment of prescribed fees as indicated in the Order of Payment shall be done  
534 through the following payment channels based on existing FDA issuances:  
535
- 536 a. Through Over-the Counter at Landbank of the Philippines (LBP) using  
537 the LBP Oncoll Payment Slip;
  - 538 b. Through Online LBP Link.BizPortal; or
  - 539 c. Through Online Bills payment (Bancnet)

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2. The deadline of payment shall be reflected in the generated Order of Payment following the successful application, wherein seven (7) calendar days shall be provided for all applications.
3. For renewal application, the establishment shall ensure that the payment shall be made before the expiration date of the LTO, otherwise, rule under Section VII.D.8 of this Order shall be applied.
4. Application payments made including but not limited to the following, shall not be accepted and posted in the system:
  - a. Application payments with incomplete/insufficient amounts paid;
  - b. Application payments with an incorrect reference number provided;
  - c. Application payments made through an unauthorized payment channel;
  - d. Application payments made beyond the validity of the issued FDA Order of Payment; and
  - e. Such other cases as determined by the FDA.
5. Changes and/or addition to the existing FDA payment channels shall be announced through a separate issuance.

**E. Inspection**

1. The conduct of pre-licensing inspection to all FDA-covered establishments under Section III of this Order shall be required, wherein initial verification of compliance with technical requirements and applicable standards of the establishments shall be checked.
2. Pre-licensing inspection for all FDA-covered establishments applying for applicable major variations as enumerated under Annex C of this Order shall also be conducted as determined by the FDA.
3. For renewal application and minor variation, routine inspection shall be conducted within the validity period of the existing LTO. Likewise, the risk-based inspection for all types of establishments within the validity of the LTO shall be conducted in reference to the criteria and risk matrixes provided by the FDA.
4. All FDA-covered establishments shall ensure that the Site Master File, Risk Management Plan, and Floor plan, if applicable, are developed and readily available at all times.
5. The FDA shall have the authority to enter any covered establishment engaging in FDA-regulated activities involving health products during operating hours to conduct routine or spot check inspections.
6. All covered establishments shall ensure that physical sites where the FDA-licensed activities take place are always readily accessible for the conduct of applicable site inspections prior, during, and after the issuance of the LTO. The absence of the declared physical site during inspection shall be one of the grounds for disapproval of the application for LTO.

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7. All licensed Manufacturers shall be granted an LTO based on the satisfactory compliance to the administrative and technical requirements set by the FDA in order to operate a manufacturing plant. A Certificate of GMP Compliance shall only be issued upon demonstration of satisfactory compliance with GMP standards and effective within the validity of the current LTO, following the conduct of a facility inspection. Thereafter, the Certificate of GMP Compliance shall be issued upon every renewal of the LTO; provided an inspection has been conducted by the FDA upon a favorable recommendation on the GMP Compliance of the facility.

**F. Evaluation**

The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.

**G. Checking of Application Status**

The applicant may check and verify the status of application on the FDA available online application platforms. The simplified checking of application status through online transactions is compliant with the Zero-Contact policy provided under RA 11032.

**H. Releasing and Printing of LTO**

The FDA shall send the approved LTO to the registered e-mail address of the applicant. Likewise, it shall be officially accessed through the FDA available online application platforms. The printing of the emailed and approved LTO shall be the sole responsibility of the owner of the establishment, thus the FDA shall no longer re-issue or provide certified true copies of the authorization/s.

**I. Validity of the LTO**

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

<b>INITIAL LTO</b>	<b>5 YEARS</b>
<b>RENEWAL LTO</b>	<b>10 YEARS</b>

2. The validity period of the existing LTO provided to the establishments corresponds to the same validity period as the variations made by the establishments.
3. Corresponding fees and other charges for the application of LTO shall be governed by FDA existing issuances.

**J. Cancellation of the issued LTO**

**1. Effect of LTO Cancellation**

Any cancelled LTO shall have the effect of non-possession of an LTO as an establishment. Thus, any establishment found to be operating their business without the necessary LTO upon inspection shall be in violation of the provision of RA 9711



636 and other related FDA Issuances and shall be penalized under existing laws, rules,  
637 and regulations.

638  
639 **2. The LTO shall be cancelled due to the following instances:**  
640

- 641 a. The application requirements submitted show that the establishment
- 642 does not meet the required technical requirements or appropriate
- 643 standards;
- 644 b. The applicant made misrepresentations, false entries, or withheld any
- 645 relevant data contrary to the provisions of the law, RA 9711, and its IRR,
- 646 or appropriate rules and regulations;
- 647 c. The owner has violated any of the terms and conditions of its license;
- 648 d. Non-compliance with any of the provided guidelines of this Order; and
- 649 e. Such other analogous grounds or causes as determined by the FDA.

650  
651 When the license is cancelled, either through an inspection verification or voluntarily,  
652 the FDA shall retain jurisdiction over violations committed by the establishments while it was  
653 in operation.

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656 **VIII. PENALTY CLAUSE**

657  
658 Sanctions over violations of any of the provisions of this Administrative Order shall be  
659 based on the Rules of Administrative Procedure provided in the IRR of RA 9711.

660  
661  
662 **IX. TRANSITORY PROVISION**

- 663
- 664 **A.** All existing applications for LTO of establishments enumerated in Section III received
- 665 prior to the effectivity date of this Order shall be processed according to DOH AO No.
- 666 2020-0017.
- 667
- 668 **B.** All major and minor variation applications received upon the effectivity of this Order
- 669 for LTOs previously issued based on DOH AO No. 2020-0017 shall be subject to the
- 670 updated guidelines as stipulated in this Order.
- 671
- 672 **C.** Pre-licensing inspections for Manufacturers are still to be required. The conduct of
- 673 pre-licensing inspections for other covered establishments shall be on pilot
- 674 implementation, which shall be initially conducted to all covered drug establishments
- 675 during the period of one (1) year from the effectivity of this Order. Post-
- 676 implementation review shall be conducted to assess the effectiveness of the pilot
- 677 implementation.
- 678
- 679 **D.** The implementing guidelines for the conduct of pre-licensing inspections for all FDA-
- 680 covered establishments shall be issued through separate guidelines.
- 681
- 682
- 683
- 684

685 **X. REPEALING CLAUSE**

686

687 AO No. 2020-0017 entitled, “Revised Guidelines on the Unified Licensing Requirements  
688 and Procedures of the Food and Drug Administration Repealing Administrative Order No.  
689 2016-0003” and *Section III.Last Par.* of FDA Circular No. 2021-0021<sup>6</sup> are hereby repealed.  
690 Other issuances or parts thereof, pertaining to specific guidelines for certain establishments  
691 which are found to be inconsistent with the provisions of this AO are hereby repealed  
692 accordingly.

693

694

695 **XI. SEPARABILITY CLAUSE**

696

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

701

702

703 **XII. MONITORING AND EVALUATION**

704

705 Within three (3) years of its implementation, this Order shall be reviewed and evaluated  
706 to determine whether the policy’s objectives, impact, and effectiveness are achieved.

707

708

709 **XIII. EFFECTIVITY**

710

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

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

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<sup>6</sup> Guidelines on the Licensing of Retailers of Medical Devices in the Philippines (Section III, last par. “In consonance with AO No. 2020-0017, this FDA Circular shall not cover grocery stores, supermarkets, convenience stores, chandler, kiosks, and other similar stores. However, although these establishments are exempted from securing the LTO, they shall be held liable and shall be considered violating the FDA regulations if they sell unregistered/unnotified medical devices”)

## ANNEX A

### A. REQUIREMENTS FOR INITIAL LICENSE TO OPERATE APPLICATION

#### 1. eApplication Form through the FDA Available Online Application Platforms

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 B

#### 2. Proof of Business Name Registration

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 issued by the Department of Trade and Industry (DTI);
- b. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;
- 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.

#### 3. 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.

#### 4. Proof of Capitalization for Manufacturers, Traders, CROs, and Sponsors

Proof of Capital Investment such as the latest audited Financial Statement with Balance Sheet (in pdf) or duly notarized Statement/Certification of Initial Capitalization, for those newly-opened establishments shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees.

#### 5. The following documents shall be presented during inspection for examination or review, when required:

##### a. Risk Management Plan (RMP) for the following establishments:

- i. Manufacturers of drugs, medical devices, cosmetics, and household urban hazardous substances (HUHS) including household/urban pesticides (HUPs) and toys and childcare articles (TCCAs);
- ii. Medium and large food manufacturers;
- iii. Traders and Distributors (importers, exporters, and/or wholesalers) of drugs, medical devices, foods, cosmetics, and HUHS including HUPs and TCCAs

- b. **Site Master File (SMF) and floor plan/plant layout** for the following establishments:
  - i. Manufacturers including packers and repackers of drugs, medical devices, cosmetics, and HUHS including HUPs and TCCAs;
  - ii. Medium and large food manufacturers;
6. For RONPD establishments with a pharmacist handling multiple RONPDs, list of all outlets including the Name of Establishment, Address, Day and Time of shift and LTO number.
7. For Food Business Operators and Medical Device Retailers, Notarized Contract of Agreement/Appointment or Authorization Letter/Distributorship Agreement and Notarized Franchise Agreement provided that the following conditions are met:
  - a. Notarized Franchise Agreement – The business name of the establishment reflected in the LTO shall be based on the trade name indicated in the Franchise Agreement. In addition, it must be consistent with the business name registration.
  - b. Notarized 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.
8. Payment of appropriate fees.

## **B. REQUIREMENTS FOR RENEWAL LICENSE TO OPERATE APPLICATION**

### **1. eApplication Form through the FDA Available Online Application Platforms**

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
1. For Food Business Operators, Financial Statement
  2. Payment of appropriate fees



## ANNEX B

### QUALIFIED PERSON QUALIFICATIONS AND CREDENTIAL REQUIREMENTS

Type of Establishment	Qualified Person	Qualification/Requirement
<p><b><u>CDRR</u></b>  Drug Manufacturer, Trader and Distributor (wholesaler, importer, exporter), CROs and Sponsors, drug outlet, and RONPD</p> <p>Veterinary Drug Retailers and Veterinary RONPD</p>	<p>Registered Pharmacists (RA 10918)</p> <p>Licensed Doctor of Veterinary Medicine (RA No. 9268)</p>	<p>a. Professional Regulation Commission (PRC) Identification Card (ID)</p> <p>b. Seminar/training certificate, learning and development activities on drug safety, quality, and efficacy and other applicable trainings (e.g., Training for Pharmacy Assistant, Basic and Advance Course on Good Clinical Practice for CROs/ sponsors)</p> <p>c. Certificate of Completion as provided by the FDA</p> <p>d. Proof of termination of employment if previously connected with another pharmacy/establishments</p>
<p><b><u>CFRR</u></b>  Food Manufacturer, Trader and Distributor (Wholesaler, Importer, Exporter)</p>	<p>Preferably a graduate of food-related courses including but not limited to food technology, food and nutrition, chemistry, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture (RA 10611).</p>	<p>a. Seminar/training certificate on food safety, GMP or HACCP given by the academe, WHO, FAO, NGOs, cooperative, food industry organizations, or professional organizations</p> <p>b. Certificate of Completion as provided by the FDA</p>
<p><b><u>CDRRHR</u></b></p> <ul style="list-style-type: none"> <li>• 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"</li> </ul>	<p>Optometrist</p>	<p>PRC ID</p>
<ul style="list-style-type: none"> <li>• Manufacturer, Trader, and Distributor (Wholesaler, Importer,</li> </ul>	<p>Graduate of engineering courses preferably chemical, sanitary, civil, and mechanical, or other science</p>	<p>PRC ID for professions with Board/Licensure examination or Diploma for profession without</p>

<p>Exporter) of health-related devices specifically:</p> <ul style="list-style-type: none"> <li>- Equipment or devices used for treating sharps, pathological and infectious wastes</li> <li>- Water purification treatment devices and/or systems</li> </ul>	<p>courses relevant to the device to be distributed</p>	<p>Board/Licensure examination. For water treatment devices, a copy of diploma shall be provided.</p>
<ul style="list-style-type: none"> <li>• Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) and Retailer of medical devices</li> </ul>	<ul style="list-style-type: none"> <li>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</li> <li>b. Engineering profession that includes but not limited to EE, ECE, ME, CoE, CHE, SE, Computer Science, and Chemistry</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>b. PRC ID for professions with Board/Licensure exam or Diploma for profession without Board/Licensure exam</li> </ul>
<b><u>CCHUHSRR</u></b>		
<ul style="list-style-type: none"> <li>• Manufacturer of Cosmetic establishments</li> </ul>	<p>Registered Chemist, Chemical Engineer, or Pharmacist</p>	<p>Valid PRC ID</p>
<ul style="list-style-type: none"> <li>• Trader and Distributor (wholesaler, importer, exporter) of Cosmetic establishments</li> </ul>	<p>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</p>	<ul style="list-style-type: none"> <li>a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and</li> <li>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</li> </ul>

		Authorities, international organizations
<ul style="list-style-type: none"> <li>• Manufacturer, trader, and distributor (wholesaler, importer, exporter) Household/Urban Hazardous Substances</li> </ul>	<b>For HUHS</b> - 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
	<b>For HUP</b> - 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.
	<b>For TCCA</b> - Bachelor's degree with verifiable, recognized, and updated trainings on the safety, quality, and use of TCCA	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 TCCA, safety, quality, and use, given by the academe, industry organization, professional organization,

		National Authorities, organizations	Regulatory international
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When applicable, the following information may be requested by the FDA in the Application Form	
Drug Manufacturer	<ul style="list-style-type: none"> <li>a. Production Manager/head</li> <li>b. Quality Assurance Manager/head</li> <li>c. Quality Control Manager/head</li> <li>d. Authorized person for batch release</li> <li>e. Pharmacovigilance officer</li> </ul>
Food Manufacturer	<ul style="list-style-type: none"> <li>a. Production Manager/head</li> <li>b. Quality Assurance Manager/head</li> <li>c. Quality Control Manager/head</li> <li>d. Food Safety Officer</li> <li>e. Any designated senior technical personnel</li> </ul>
Medical Device Manufacturer	<ul style="list-style-type: none"> <li>a. Production Manager/head</li> <li>b. Quality Assurance Manager/head</li> <li>c. Quality Control Manager/head</li> </ul>
Cosmetic and HUHS Manufacturer	<ul style="list-style-type: none"> <li>a. Production Manager/head</li> <li>b. Quality Control and/or Assurance Manager/head</li> <li>c. Product Safety Assessor</li> </ul>

**ANNEX C**

**LIST OF REQUIREMENTS FOR SPECIFIC VARIATION IN THE LTO**

**1. Major Variation for Local Manufacturers**

<b>Type of Variation</b>	<b>Requirement</b>
<p><b>Transfer of Location of Manufacturing/Packing/Repacking Plant</b></p> <p>Physical transfer of the establishment (and may entail changes in the previously approved address)</p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Proof of business address reflecting the new plant location:               <ol style="list-style-type: none"> <li>a. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new plant location;</li> <li>b. For SEC-registered establishments:                   <ul style="list-style-type: none"> <li>- Amended Articles of Incorporation (if transferred from one city/municipality/province); or</li> <li>- Updated General Information Sheet (GIS) from SEC (if transferred from one city/municipality/province)</li> </ul> </li> </ol> </li> </ol> <p>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.</p> <ol style="list-style-type: none"> <li>3. Updated Site Master File</li> <li>4. Updated floor plan or plant lay-out</li> <li>5. Payment of appropriate fees.</li> </ol>
<p><b>Expansion of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity</b></p> <ul style="list-style-type: none"> <li>• Expansion shall refer to expansion made which is adjacent to the existing location of the establishment</li> <li>• Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.)</li> </ul>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Updated Site Master File and Floor Plan showing the expansion made to be presented upon inspection</li> <li>3. Payment of appropriate fees.</li> </ol> <p>For drug and food products, satisfactory laboratory analysis of not more than one (1) year from the issuance shall also be presented</p>

<ul style="list-style-type: none"> <li>• Change in manufacturing activity shall refer to an additional activity that a manufacturer engages in (e.g., LTO as Manufacturer-Repacker to Manufacturer-Packer)</li> </ul>	
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**2. Minor Variation**

<p><b>Transfer of Location of Offices</b></p> <p>Physical transfer of the office of the establishment</p>	<p><b>Proof of business address reflecting the new office location:</b></p> <ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. <b>For Single Proprietorship</b> Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location;</li> <li>3. <b>For SEC-registered establishments</b> <ol style="list-style-type: none"> <li>b. Amended Articles of Incorporation (if transferred from one city/municipality/province); or</li> <li>c. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality)</li> </ol> </li> <li>4. PEZA Certificate reflecting the new office address, if applicable</li> <li>5. Notarized Contract of Lease or any proof of ownership of the new office location</li> <li>6. Payment of appropriate fees.</li> </ol> <p>If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location.</p>
<p><b>Transfer of Location of Drug Retailers</b></p> <p>Physical transfer of the drug retailer establishment</p>	<p><b>Proof of business address reflecting the new location of drug retailer:</b></p> <ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. <b>For Single Proprietorship</b> Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location;</li> </ol>

	<p>Permit/Clearance reflecting the new location of drug retailer;</p> <p><b>3. For SEC-registered establishments</b></p> <p>d. Amended Articles of Incorporation (if transferred from one city/municipality/province); or</p> <p>e. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality)</p> <p><b>4. Payment of appropriate fees.</b></p> <p>If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new location of drug retailer.</p>
<p><b>Change of Distributor Activity</b></p> <p>Shall refer to an additional/deletion of/change in activity that the distributor engages in.</p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Contract Agreements showing change in activity</li> <li>3. Payment of appropriate fees.</li> </ol>
<p><b>Transfer/Addition of Warehouse</b></p> <p>Physical transfer and addition of the warehouse of the establishment</p>	<ol style="list-style-type: none"> <li>1. Application form</li> <li>2. Business permit/Mayor's permit/Barangay Clearance reflecting the new address</li> <li>3. Contract of Lease including the warehouse address</li> <li>4. PEZA certificate reflecting the new warehouse address, if applicable</li> <li>5. Payment of appropriate fees</li> </ol>
<p><b>Additional Drugstore Activities</b></p>	<ol style="list-style-type: none"> <li>1. Application Form</li> <li>2. Additional Credentials of Pharmacist, as applicable</li> <li>3. Other documents related or specific to the additional activity, such as but not limited to: <ol style="list-style-type: none"> <li>a. Adult vaccination <ol style="list-style-type: none"> <li>i. Standard Operating Procedure (SOP) for the cold chain management following FDA Circular 2021-003 (Revised Guidelines on the Cold Chain Management for</li> </ol> </li> </ol> </li> </ol>



	<p>Pharmaceutical Products and Establishments)</p> <ul style="list-style-type: none"> <li>ii. SOP for the vaccination/immunization activities</li> <li>iii. Certification as a Certified Immunizing Pharmacist</li> </ul> <p>b. Dispense Vaccines and Biologicals</p> <ul style="list-style-type: none"> <li>i. SOP for the cold chain management following FDA Circular 2021-003</li> </ul> <p>c. Mobile Pharmacy</p> <ul style="list-style-type: none"> <li>i. SOP for the conduct of mobile pharmacy activities</li> <li>ii. Image/Picture with description of the mobile pharmacy vehicle</li> <li>iii. Credentials of the supervising pharmacist of the mobile pharmacy</li> </ul> <p>d. Online Ordering and Delivery</p> <ul style="list-style-type: none"> <li>i. SOP for the online ordering and delivery activities</li> <li>ii. Website link</li> <li>iii. Website screenshot showing the ordering system and the placement of LTO details</li> <li>iv. Other documents as required in separate issuance for e-Pharmacy</li> </ul> <p>e. Sterile Compounding and Non-Sterile Complex Compounding</p> <ul style="list-style-type: none"> <li>i. SOP for the compounding activities.</li> </ul> <p>4. Payment of appropriate fees.</p> <p>NOTE: The establishment shall be inspected for GMP clearance prior approval of the variation.</p>
<p><b>Expansion of Office Establishments and Drug Retailers</b></p> <p>Shall refer to expansion made which is adjacent to the existing location of the establishment</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Current floor plan</li> <li>3. Expansion floor plan</li> <li>4. Payment of appropriate fees</li> </ul>
<p><b>Change in ownership of the establishment</b></p> <p>Change only in the business name of the establishment</p>	<ul style="list-style-type: none"> <li>1. Business name registration reflecting new ownership;</li> <li>2. Any proof of the transfer of ownership such as any of the following;</li> </ul>

	<ul style="list-style-type: none"> <li>i. Deed of Sale or Assignment or Transfer of Rights/Ownership;</li> <li>ii. Memorandum of Agreement (MOA);</li> <li>iii. Notarized Affidavit of the owner, proprietor, chairman or CEO of the establishment validating the transfer.</li> </ul> <p>3. Payment of appropriate fees</p>
<p><b>Zonal Change in Address</b></p> <p>Change of the name/number of the street/building without physical transfer of the establishment</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. 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</li> <li>3. Payment of appropriate fees</li> </ul>
<p><b>Change of Qualified Person</b></p> <p>Change in the identified qualified person initially registered with the FDA</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Valid PRC ID</li> <li>3. Proof of termination of employment, if previously connected with another pharmacy/establishment or Notarized Waiver of Liability/ Sworn Statement stating the QP is effectively resigned from the previous employer.</li> </ul> <p>For Pharmacists handling multiple RONPDs: List of all RONPDs handled by the Pharmacist (to include, Name of establishment, Address, Day and Time of shift and LTO Number)</p> <p>4. Payment of appropriate fees.</p>
<p><b>Change of Authorized Person</b></p> <p>Change in the authorized person initially registered with the FDA</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Valid government issued ID</li> <li>3. Payment of appropriate fees.</li> </ul>
<p><b>Addition/Deletion of Sources and Products</b></p> <p>Addition/deletion of source(s) and product(s) in the previous/existing list</p>	<ul style="list-style-type: none"> <li>1. Application Form</li> <li>2. Notarized Valid Contract Agreement; 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</li> <li>3. Payment of appropriate fees.</li> </ul>