



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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2
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
94
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 System¹.

- 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 ²(ASIN Law) and its revised IRR;
 - 2. Bottled Water Manufacturers shall follow AO No. 18-A s. 1993³;
 - 3. Radiation facilities shall follow AO No. 2020-0035⁴
 - 4. Operators of pest control for non-agricultural purposes shall follow DOH AO No. 2019-0010⁵;
 - 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.

¹ A strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other health facilities.
² An Act Promoting Salt Iodization Nationwide (ASIN)
³ Standards of Quality and Requirements for the Processing, Packaging, and Labelling of Bottled Drinking Water
⁴ Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorization
⁵ 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).
146
- 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.
151
- 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.
158
- 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.
170
- 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.
173
- 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.
178
- 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.
182
- 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.

259

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.
298
- 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.
313
- 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.

- 341 d. All CROs, Sponsors and other concerned entities shall adhere to existing
342 ethical and scientific quality standards of safety and efficacy in the
343 conduct of clinical trials.
- 344 e. No CRO or Sponsor shall be involved in the conduct of clinical trials
345 without a license from the FDA. Licensed CROs/Sponsors that
346 import/export products subject to clinical trials are no longer required to
347 secure a separate LTO.
- 348 f. All FDA-licensed drug retailers (drugstore, pharmacy, botica) or
349 RONPD that also offer to sell medical device products shall secure a
350 separate LTO from the FDA as Retailer of Medical Devices;
- 351 g. All FDA-required information, education, and communication
352 campaign materials shall be displayed in the establishment's
353 conspicuous area.
- 354 h. All drugstores shall comply with the following:
- 355 i. Designated dispensing areas that are sufficiently secured to
356 prevent unauthorized access during operating hours. This is
357 also to ensure the safekeeping of specified health products to
358 be supplied or dispensed by retail at or from the drugstores;
- 359 ii. Applicable establishment layouts that allow for the orderly
360 arrangement of specified health products to be supplied or
361 dispensed by retail at or from the drugstores;
- 362 iii. Appropriate storage facilities in accordance with the
363 conditions approved by the FDA for the storage of specified
364 health products; and
- 365 iv. A system for proper safekeeping and maintenance of the
366 records of the specified health products stored at the
367 drugstores, including arrangements to audit the records shall
368 be adequately provided to ensure integrity.

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

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- 372 a. All licensed Cosmetic/HUHS establishments with refilling activity shall
373 only be applied as a Cosmetic/HUHS Manufacturer.
- 374 b. Specific guidelines on the licensing and inspection of Cosmetic/HUHS
375 Manufacturers/Refillers shall be issued through separate issuances.
- 376

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

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- 379 a. All establishments shall comply with the current guidelines on general
380 principles of food hygiene including the provisions provided for by
381 Presidential Decree No. 856 on the Code of Sanitation and other general
382 requirements.
- 383 b. As appropriate, all Food Business Operators (FBOs) shall comply with
384 the relevant standards and requirements of Hazard Analysis Critical
385 Control Point (HACCP), Sanitary Standard Operating Procedures
386 (SSOP), and other good practice regulations and guidelines expounded
387 in Section VI of this AO, to ensure the safety and quality of products.
- 388 c. LTO is a requirement before a food establishment can join food trade
389 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.
395

396 **4. For Medical Device establishments:**

- 397
- 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.
410

411 **B. The Qualified Personnel of the establishments shall ensure compliance with the**
412 **following:**

- 413
- 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.
418
 - 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:-
430
 - 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**

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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**

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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.
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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:

INITIAL LTO	5 YEARS
RENEWAL LTO	10 YEARS

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.

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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.

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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**

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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.

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662 **IX. TRANSITORY PROVISION**

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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.
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685 **X. REPEALING CLAUSE**

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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. 2021-0021⁶ 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.

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695 **XI. SEPARABILITY CLAUSE**

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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.

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703 **XII. MONITORING AND EVALUATION**

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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.

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709 **XIII. EFFECTIVITY**

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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

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Officer-in-Charge - Secretary of Health

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⁶ 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”)