



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER

No. _____

SUBJECT: Amendment to Administrative Order No. 2020-0017 entitled, “Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003”

I. RATIONALE

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

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

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

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

II. OBJECTIVES

The objectives for issuing this Administrative Order are as follows:

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

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52 **III. SPHERE OF APPLICATION**
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54 A. The following establishments, whether public or private, shall be covered by this
55 Order:

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57 1. Manufacturers, including Packers/Repackers, and Refurbishers of medical
58 devices;
59 2. Cosmetic/HUHS Manufacturers/Refillers;
60 3. Traders;
61 4. Distributors as Importers, Exporters, and/or Wholesalers;
62 5. Food Business Operators;
63 6. Drug outlets, such as drugstores, pharmacies (community, or institutional); or
64 *boticas*, and retail outlets for non-prescription drugs (RONPD);
65 7. Retailers of Medical Devices including groceries, convenience stores, and
66 supermarkets; and
67 8. Clinical Research Organizations (CROs) and Sponsors
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69 B. The scope of the health products shall include, but not be limited to:

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71 1. Under the CCHUHSRR, all cosmetic products, household/urban hazardous
72 substances (HUHS), including household/urban pesticides, and toys and childcare
73 articles;
74 2. Under the CDRR, all drugs, including vaccines, biologics, veterinary medicines
75 and animal health products, medical gases, traditional medicine, and herbal
76 medicines;
77 3. Under the CDRRHR, all medical devices, radiation emitting devices, in-vitro
78 diagnostic devices and reagents; refurbished medical devices; custom-made
79 medical devices; equipment or devices used for treating sharps, pathological and
80 infectious wastes, water treatment devices/systems; and other health-related
81 devices as determined by the FDA; and
82 4. Under the CFRR, all processed food products, food supplements, raw materials,
83 ingredients and additives for food.
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85 This does not preclude the FDA from updating the scope of health products and
86 establishments which requires regulation in accordance with the FDA rules and regulations.
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88 C. The following shall NOT be covered by this Order:

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

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

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

IV. DEFINITION OF TERMS

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

- A. **Authorized Person** - refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity.
- B. **Contract Research Organization (CRO)** – refers to a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor’s trial-related duties and functions (ICH GCP 1.20).
- C. **Custom-Made Medical Device** – refers to any device specifically made in accordance with a duly qualified medical practitioner’s written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. For the purpose of clarity, mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made medical devices.
- D. **Distributor/Exporter** - refers to any establishment that exports raw materials, active ingredients and finished products for distribution to other establishments outside the country.
- E. **Distributor/Importer** – refers to any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed establishments
- F. **Distributor/Wholesaler** - refers to any establishment that procures raw materials, active ingredients and/or finished products from a local FDA-licensed establishments for local distribution on wholesale basis.

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- 152 G. **FDA Academy** - refers to an office under the Policy and Planning Service of the FDA
- 153 that offers health regulatory webinar and technical training to external Stakeholders.
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- 155 H. **Initial Application** or **Original Application** - refers to the LTO applied to FDA prior
- 156 to engaging in the business or operation involving the manufacture, importation,
- 157 exportation, sale, offer for sale, distribution, transfer, and where applicable the use,
- 158 testing, promotion, advertisement, and/or sponsorship of health products.
- 159
- 160 I. **Major Variation** covers changes in the operations of the establishment that may affect
- 161 significantly and/or directly the aspects of safety and quality and when applicable,
- 162 efficacy of the products.
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- 164 J. **Minor Variation** covers changes in administrative matters and/or changes in the
- 165 operations of the establishments but with minimal impact on the safety, quality, and
- 166 when applicable, the efficacy of the products.
- 167
- 168 K. **Manufacturer** - refers to any establishment engaged in any and all operations
- 169 involved in the production of health products including preparation, processing,
- 170 compounding, formulating, filling, packing, repacking, altering, ornamenting,
- 171 finishing, and labeling with the end in view of its storage, sale or distribution.
- 172 Provided, that the term shall not apply to the compounding and filling of prescriptions
- 173 in drugstores and hospital pharmacies.
- 174
- 175 L. **Repacker** - refers to any establishment that repacks a finished product into smaller
- 176 quantities in a separate container and/or secondary packaging, including but not
- 177 limited to relabeling, stickering, and bundling for promo packs with the end view of
- 178 storage, distribution, or sale of the product.
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- 180 M. **Packer** – refers to any establishment that packages bulk product into its immediate
- 181 container with the end view of storage, distribution, or sale of the product.
- 182
- 183 N. **Pre-licensing Inspection** - refers to an organized examination or formal evaluation of
- 184 the facility(ies), warehouses, and/or offices of an establishment applying for an initial
- 185 application or a major variation of its existing license.
- 186
- 187 O. **Qualified Person (QP)** refers to an organic or full-time employee of the establishment
- 188 who possesses technical competence related to the establishment's activities and
- 189 health products by virtue of his profession, training or experience. A qualified person
- 190 has the responsibility to comply with the technical requirements of the FDA or discuss
- 191 or clarify matters with the FDA when submitting technical requirements or engage the
- 192 FDA officials when conducting inspection or Post-Marketing Surveillance (PMS)
- 193 activities. The qualified person may also be the duly Authorized Person of the
- 194 establishment.
- 195
- 196 P. **Renewal Application** refers to the LTO applied to FDA before the expiration of the
- 197 validity of the current LTO for the business operation continuity involving
- 198 manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and
- 199 where applicable the use, testing, promotion, advertisement, and/or sponsorship of
- 200 health products.

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- Q. **Refurbished Medical Device** - refers to the medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it: a.) stripping into component parts or subassemblies; b.) checking their suitability for reuse; c.) replacement of components/sub-assemblies not suitable for reuse; d.) assembly of the reclaimed and/or replacement components/sub-assemblies; e.) testing of the assembled device against either original or revised release criteria; or f.) identifying an assembled medical device as a refurbished medical device. (ASEAN Medical Device Directive, 2015).
- R. **Retailer** - refers to any establishment which sells or offers to sell any health product directly to the general public.
- S. **Risk Management Plan** refers to a set of health product vigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to health products, and the assessment of effectiveness of those interventions. The risk management plan is a requirement for the issuance of the appropriate authorization.
- T. **Routine Inspection** - refers to the usual process, which may be physical or remote, of the facility(ies), warehouses, and/or offices of an establishment, which is conducted by the FDA at any time during the validity of a license of an establishment.
- U. **Site Master File** - refers to the specific information about the quality assurance, the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of an operation is carried out on the site, a Site Master File needs only describe those operations, e.g., analysis, packaging, for documentation.
- V. **Special Permit** – refers to a form of authorization granted to entities that provide drugs to be used only for a specific purpose, such as but not limited to, either medical missions, employee or constituent vaccinations, or other health-related programs and are not for sale or resale. For other purposes, such as promotion, advertising, or sponsorship of drug product, a Sales Promotions Permit shall be secured in lieu of Special Permit.
- W. **Sponsor** - refers to an individual, company, institution, organization or an entity which takes the responsibility for the initiation, management, and/or financing of a clinical trial.
- X. **Trader** refers - to an establishment which is a registered owner of a health product and procures the raw materials and packing components and provides the production, monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed Manufacturer. In addition, a trader may also engage in distribution and/or marketing of its products.
- Y. **Virtual Office** refers to an off-site business location where certain services of the establishments are provided.

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

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

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

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

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

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

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

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

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297 G. The establishment shall inform the FDA of any changes or variations made to its
298 license and a corresponding application shall likewise be made for re-issuance of an
299 LTO.
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- 301 H. All licensed Manufacturers shall be granted an LTO based on the minimum
302 requirements set by FDA in order to operate a manufacturing plant. A Certificate of
303 GMP Compliance shall only be issued upon demonstration of satisfactory compliance
304 with GMP standards and effective within the validity of the current LTO. Thereafter,
305 the Certificate of GMP Compliance shall be issued each time the LTO is renewed.
306
- 307 I. Manufacturers and Distributors shall declare on their application the list of sources
308 and name of products for each source (regardless whether finished/semi-finished/raw
309 materials/active pharmaceutical ingredients/excipients).
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- 311 J. All FDA-required information, education, and communication campaign materials
312 shall be displayed in the establishment's conspicuous area.
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- 314 K. For Drug establishments:
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- 316 1. All drug or pharmaceutical establishments based on Section 31 of RA 10918 or the
317 Philippine Pharmacy Act, whether public or private, shall be under the supervision
318 of a registered pharmacist when operating or open for business, unless otherwise
319 allowed by other pertinent laws or regulations.
 - 320 2. All entities, whether government or non-government, that regularly procure drugs
321 on wholesale basis from appropriate FDA-duly licensed drug establishments for
322 distribution to their constituents shall be licensed as a drug distributor.
 - 323 3. All drug distributors shall not sell directly to the general public or consumer, unless
324 they have an LTO as drugstores.
 - 325 4. All CROs, Sponsors and other concerned entities shall adhere to existing ethical
326 and scientific quality standards of safety and efficacy in the conduct of clinical
327 trials.
 - 328 5. No CRO and Sponsor shall be involved in the conduct of clinical trials without a
329 license from the FDA. Likewise, no CRO and Sponsor shall be involved in the
330 conduct of clinical trials without a license from the FDA. Licensed CROs/Sponsors
331 that import/export product subject for clinical trials are no longer required to secure
332 a separate LTO.
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- 334 L. For Cosmetic/HUHS establishments:
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- 336 1. All establishments engaged in the compounding/mixing of Cosmetic/HUHS
337 products shall secure an LTO as Cosmetic/HUHS Manufacturer.
 - 338 2. All licensed Cosmetic/HUHS establishments with refilling activity shall only be
339 applied as a Cosmetic/HUHS Manufacturer.
 - 340 3. All Cosmetic/HUHS establishments applying for an initial application as a
341 Manufacturer shall declare the refilling activity if applicable. On the other hand,
342 all Cosmetic/HUHS Manufacturers with existing LTO shall apply a variation
343 application to add refilling activity, if applicable.
 - 344 4. Specific guidelines on the licensing and inspection of Cosmetic/HUHS
345 Manufacturers/Refillers and establishments manufacturing customized cosmetics
346 shall be issued through separate issuances.
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351 M. For Food Business Operators:

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- 353 1. All establishments shall comply with the general principles of food hygiene
 - 354 including the provisions provided for by Presidential Decree No. 856 on the Code
 - 355 of Sanitation and other general requirements.
 - 356 2. As appropriate, all Food Business Operators shall comply with the relevant
 - 357 standards and requirements of Hazard Analysis Critical Control Point (HACCP),
 - 358 Sanitary Standard Operating Procedures (SSOP), and other good practice
 - 359 regulation and guidelines expounded in Section V.5 of this AO, to ensure safety
 - 360 and quality of products.
 - 361 3. LTO is a requirement before a food establishment can join food trade and
 - 362 exhibitions, conduct market research or testing of unregistered processed food
 - 363 products. CPR shall be required if the imported product is offered for sale or for
 - 364 “free tasting” during the food trade and exhibitions.
 - 365 4. All establishments shall comply with food safety standards recognized by the Food
 - 366 and Agriculture Organization of the World Health Organization.
 - 367

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

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

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379 1. Initial LTO

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

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- 392 a. Accomplished eApplication Form with Declaration of Undertaking; and
- 393 b. Payment of Fees
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395 3. Variation

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

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

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

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

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

Guidance for the above requirements is attached as Annex A.

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

1. Filing of Applications

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

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

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

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

- 452 c. For applications with complete and correct documentary requirements and
453 posted payment, the FDA shall issue an Acknowledgement Receipt containing
454 the name of the personnel who received the application, reference number,
455 agency logo, the date and time of application, payment, and the statement of
456 completeness of the documents submitted. An application shall be considered
457 filed once the applicant receives the Acknowledgement Receipt.
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- 459 d. All transactions with the FDA shall be communicated to the applicants using
460 the registered e-mail address provided during the initial application. The
461 applicant shall be responsible in making sure that the e-mail address is within
462 the scope and access of the Authorized Person/s and/or Qualified Personnel of
463 the establishment.
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- 465 e. Application for renewal shall be done within three (3) months prior to the
466 expiration of the validity date of the LTO. Applications filed after the validity
467 date of the LTO shall be subject to surcharge as prescribed in RA 9711 and its
468 IRR.
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- 470 f. No application for variation of LTO shall be done and shall be granted when an
471 establishment has a pending application for renewal of LTO, or vice versa.
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- 473 g. The applicant shall receive the LTO in their registered e-mail address and may
474 also be accessed through the FDA eServices Portal System. Upon receipt of the
475 LTO, the establishments shall print the LTO on a standard A4 size (21 cm x
476 29.7 cm) paper, on full-colored page and in portrait orientation. It shall be
477 placed on the most conspicuous place within the business establishments.
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479 C. Payment

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- 481 1. Payment of prescribed fees as indicated in the Order of Payment shall be done
482 through the following payment channels, based on AO No. 50 series 2001 and its
483 latest amendment, and other existing FDA issuances:
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- 485 a. Through Over-the Counter at LBP using the LBP Oncoll Payment Slip (to the
486 Center's LBP Clearing Account, FDA Circular No. 2013-046
487 b. Through Online LBP Link.Biz Portal
488 c. Through Online Bills payment (Bancnet)
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- 490 2. Application payment made including but not limited to the following shall not be
491 accepted and posted in the system.
492 a. Application payments with incomplete/insufficient amount paid.
493 b. Application payments with Wrong reference number provided.
494 c. Application payments made through a Wrong payment channel.
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- 496 3. Additional payment channels shall be updated through a separate issuance.
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502 D. Evaluation

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

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- 521 1. The conduct of pre-licensing inspection shall be mandatory for all Manufacturers,
- 522 Distributors, and Traders of Food, Device, Cosmetic, and Drug products prior to
- 523 the issuance of an LTO.
- 524 2. The FDA shall have the authority to enter any FDA-licensed establishments and
- 525 establishments selling FDA-regulated health products during operating hours to
- 526 conduct routine or spot check inspections.
- 527 3. A Certificate of Compliance with technical requirements shall be issued to
- 528 establishment following a satisfactory submission of documentary requirements
- 529 and compliance with technical obligations.
- 530 4. The FDA may conduct inspections in collaboration with the Local Government
- 531 Units and other agencies or offices under the DOH, Department of Agriculture,
- 532 and Department of Interior and Local Government or other enforcement agencies
- 533 as deemed necessary based on RA 9711 and other applicable laws.
- 534 5. Establishments shall not be precluded from utilizing virtual offices for selected
- 535 operations; Provided, that the establishment must have a physical site where the
- 536 FDA-licensed activity takes place prior, during, and after the issuance of the FDA
- 537 marketing authorizations. Correspondingly, it shall be the address of the physical
- 538 site which shall be reflected in the FDA-issued LTO. The FDA shall not recognize
- 539 a virtual office as the address to be reflected in all documentary requirements when
- 540 transacting with the Agency.
- 541
- 542 Covered establishments may utilize virtual offices and other online facilities, in
- 543 cases permitted by the FDA, in addition to the maintenance of a physical site.
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- 545 6. The guidelines outlining the parameters for inspection shall be issued through a
- 546 separate issuance.
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548 F. Checking of Application Status

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550 The applicant shall check or view the status of the application through the FDA

551 eServices Portal System. Personal visits shall be discouraged.

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553 G. Releasing of LTO
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555 The FDA shall send the approved LTO to the registered e-mail address of the
556 applicant and shall also be accessed through the FDA eServices Portal System.
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558 H. The validity of LTOs and the applicable fees and other charges shall be covered by the
559 latest FDA issuance.
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561 I. An LTO shall be canceled through the following instances:
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- 563 1. Automatic cancellation if the establishment failed to file an application for renewal
564 after one-hundred twenty (120) days from the date of expiration;
565 2. Upon verification of the actual status of the establishment through inspection;
566 3. Imposed by the FDA as a penalty, if warranted; and
567 4. Voluntary filing through a formal notification with the FDA based on the following
568 conditions:
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570 a. If the establishment voluntarily filed an LTO cancellation before its expiration,
571 then decided to continue the business operation after closure of the
572 establishment, the application shall be considered as “initial application”
573 without surcharge;
574 b. If the establishment voluntarily filed an LTO cancellation after its expiration,
575 then decided to continue the business operation after closure of the
576 establishment, surcharge shall be imposed. Computation of surcharge shall be
577 based on existing FDA guidelines on fees and charges.
578 5. When the license is canceled either through an inspection verification or
579 voluntarily, the FDA shall retain jurisdiction over violations committed by the
580 establishments while it was in operation.
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583 **VII. PENALTY CLAUSE**
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585 Sanctions over violations of any of the provisions of this Administrative Order shall be
586 based on the Rules of Administrative Procedure provided in the IRR of RA 9711.
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589 **VIII. TRANSITORY PROVISION**
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591 All existing applications for LTO deemed received prior the effectivity of this Order
592 shall be processed according to previously approved issuances.
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594 All establishments with valid LTO prior to the effectivity of this Order shall be given a
595 period of one (1) year to comply with the provisions hereof.
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598 **IX. REPEALING CLAUSE**
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600 AO No. 2020-0017 entitled, “Revised Guidelines on the Unified Licensing Requirements
601 and Procedures of the Food and Drug Administration Repealing Administrative Order No.

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

X. SEPARABILITY CLAUSE

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

XI. EFFECTIVITY

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

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Officer-in-Charge, Secretary of Health

ANNEX A

Requirements for License to Operate Application

1. Application Form

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 creates 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 or Barangay Certificate with complete business address (e.g., Mayor's Permit).

4. Proof of Capitalization for Manufacturers and Traders

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. Risk Management Plan and Site Master File for Manufacturers which shall be presented during inspection.

6. Certificate of Compliance with technical requirements after a satisfactory inspection from a pre- or post-licensing inspection.

7. For Drug establishments, list of all RONPDs handled by the Pharmacist (for pharmacists handling multiple RONPDs, include the Name of Establishment, Address, Day, and Time of shift and LTO Number)

8. Payment of appropriate fees.

ANNEX B

Qualified Person Qualification and Credential Requirements

Type of Establishment	Qualified Person	Qualification/Requirement
<u>CDRR</u> Drug Manufacturer, Trader and Distributor (wholesaler, importer, exporter), CROs and Sponsors, drug outlet, and RONPD	Registered Pharmacists (RA 10918)	<ul style="list-style-type: none"> a. Professional Regulation Commission (PRC) Identification Card (ID) 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) c. Proof of termination of employment if previously connected with another pharmacy/establishments
<u>CFRR</u> Food Manufacturer, Trader and Distributor (Wholesaler, Importer, Exporter)	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).	Seminar/training certificate on food safety, GMP or HACCP given by the academe, WHO, FAO, NGOs, cooperative, food industry organizations, professional organizations, or the FDA Academy
<u>CDRRHR</u> • Retailers of Medical Devices	Company Regulatory Officer at least college graduate	Diploma
• 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”	Optometrist	PRC ID
• Health-Related Device Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) of:	Graduate of engineering courses preferably chemical, sanitary, civil, and mechanical, or other science courses relevant to the device to be distributed	PRC ID for professions with Board/Licensure examination or Diploma for profession without Board/Licensure examination. For water treatment devices, a

<ul style="list-style-type: none"> - Equipment or devices used for treating sharps - Pathological and infectious wastes - Water treatment systems - Water treatment devices 		copy of diploma shall be provided.
<ul style="list-style-type: none"> • Medical Device Manufacturer, Trader, and Distributor (wholesaler, importer, exporter) of: <ul style="list-style-type: none"> - Radiation-emitting devices - In-vitro diagnostic reagents - Refurbished medical devices 	<ul style="list-style-type: none"> a. Registered professional or graduates in the field of health profession such as Pharmacy, Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Physical Therapy, and other allied science courses relevant to the device to be distributed b. Engineering profession that includes but not limited to EE, ECE, ME, CoE, CHE, SE, Computer Science, and Chemistry 	<ul style="list-style-type: none"> 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. b. PRC ID for professions with Board/Licensure exam or Diploma for profession without Board/Licensure exam
<u>CCHUHSRR</u>		
<ul style="list-style-type: none"> • Manufacturer of Cosmetic establishments 	Registered Chemist, Chemical Engineer, or Pharmacist	Valid PRC ID
<ul style="list-style-type: none"> • Trader and Distributor (wholesaler, importer, exporter) of Cosmetic establishments 	Registered professional or graduates in the field of allied health, chemistry, chemical engineering, or cosmetic science with verifiable, recognized, and updated trainings on the safety, quality, and use of cosmetics	<ul style="list-style-type: none"> a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on cosmetic safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations
	For HUHS - Registered professional or graduates in the	<ul style="list-style-type: none"> a. Valid PRC ID for professions with board/licensure exam or

<ul style="list-style-type: none"> Manufacturer, trader, and distributor (wholesaler, importer, exporter) Household/Urban Hazardous Substances 	field of allied health, chemistry, or chemical engineering with verifiable, recognized, and updated trainings on the safety, quality, and use of HUHS	Diploma for professions without board/licensure exam; and b. Certificate of copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on HUHS safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations
	For HUP - Registered professional or graduates of Pharmacy, Chemistry, Chemical Engineering, Toxicology, Veterinary Medicine, Agricultural Biotechnology (Entomology) and Entomology	Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam
	For TCCA - 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 Regulatory Authorities, international organizations

When applicable, the following information may be requested by the FDA in the Application Form	
Drug Manufacturer	a. Production Manager/head b. Quality Assurance Manager/head c. Quality Control Manager/head d. Authorized person for batch release e. Pharmacovigilance officer
Food Manufacturer	a. Production Manager/head b. Quality Assurance Manager/head c. Quality Control Manager/head d. Food Safety Officer

	e. Any designated senior technical personnel
Medical Device Manufacturer	a. Production Manager/head b. Quality Assurance Manager/head c. Quality Control Manager/head
Cosmetic and HUHS Manufacturer	a. Production Manager/head b. Quality Control and/or Assurance Manager/head c. Product Safety Assessor

ANNEX C

List of Requirements for Specific Variation in the LTO

1. Major Variation for Local Manufacturers

Type of Variation	Requirement
<p>Transfer of Location of Manufacturing/Packing/Repacking Plant</p> <p>Physical transfer of the establishment (and may entail changes in the previously approved address)</p>	<ol style="list-style-type: none"> 1. Application Form 2. Proof of business address reflecting the new office location: <ol style="list-style-type: none"> a. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; b. For SEC-registered establishments: <ul style="list-style-type: none"> - Amended Articles of Incorporation (if transferred from one city/municipality/province); or - Updated General Information Sheet (GIS) from SEC (if transferred from one city/municipality/province) <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> <ol style="list-style-type: none"> 3. Updated Site Master File 4. Payment of appropriate fees.
<p>Expansion of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity</p> <ul style="list-style-type: none"> • Expansion shall refer to expansion made which is adjacent to the existing location of the establishment • Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.) 	<ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File and Floor Plan showing the expansion made to be presented upon inspection 3. Payment of appropriate fees. <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"> Change in manufacturing activity shall refer to an additional activity that a manufacturer engages in (e.g., LTO as Manufacturer with additional activity as Repacker) 	
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2. Minor Variation

<p>Transfer of Location of Offices</p> <p>Physical transfer of the office of the establishment (which may also entail changes in the previously approved address)</p>	<p>Proof of business address reflecting the new office location:</p> <ol style="list-style-type: none"> Application Form For Single Proprietorship Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; For SEC-registered establishments <ol style="list-style-type: none"> Amended Articles of Incorporation (if transferred from one city/municipality/province); or Updated General Information Sheet (GIS) from SEC (if transferred from one city/municipality/province) Payment of appropriate fees. <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>Transfer of Location of Drug Retailers</p> <p>Physical transfer of the drug retailer (which may also entail changes in the previously approved address)</p>	<p>Proof of business address reflecting the new office location:</p> <ol style="list-style-type: none"> Application Form For Single Proprietorship Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; For SEC-registered establishments <ol style="list-style-type: none"> Amended Articles of Incorporation (if transferred

	<p>from one city/municipality/province); or</p> <p>e. Updated General Information Sheet (GIS) from SEC (if transferred from one city/municipality/province)</p> <p>4. Payment of appropriate fees.</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 office location.</p>
<p>Change of Distributor Activity</p> <p>Shall refer to an additional/deletion of/change in activity that the distributor engages in</p>	<ol style="list-style-type: none"> 1. Application Form 2. Contract Agreements showing change in activity 3. Payment of appropriate fees.
<p>Transfer/Addition of Warehouse</p> <p>Physical transfer and addition of the warehouse of the establishment</p>	<ol style="list-style-type: none"> 1. Application form 2. Business permit/Mayor's permit/Barangay Clearance reflecting the new address 3. Payment of appropriate fees.
<p>Additional Drugstore Activities</p>	<ol style="list-style-type: none"> 1. Application Form 2. Additional Credentials of Pharmacist, as applicable 3. Other documents related or specific to the additional activity, such as but not limited to: <ol style="list-style-type: none"> a. Adult vaccination <ol style="list-style-type: none"> i. Standard Operating Procedure (SOP) for the cold chain management following FDA Circular 2021-003 (Revised Guidelines on the Cold Chain Management for Pharmaceutical Products and Establishments) ii. SOP for the vaccination/immunization activities iii. Certification as a Certified Immunizing Pharmacist b. Dispense Vaccines and Biologicals <ol style="list-style-type: none"> i. SOP for the cold chain management following FDA Circular 2021-003 c. Mobile Pharmacy

	<ul style="list-style-type: none"> i. SOP for the conduct of mobile pharmacy activities ii. Image/Picture with description of the mobile pharmacy vehicle iii. Credentials of the supervising pharmacist of the mobile pharmacy d. Online Ordering and Delivery <ul style="list-style-type: none"> i. SOP for the online ordering and delivery activities ii. Website link iii. Website screenshot showing the ordering system and the placement of LTO details iv. Other documents as required in separate issuance for e-Pharmacy e. Sterile Compounding and Non-Sterile Complex Compounding <ul style="list-style-type: none"> i. SOP for the compounding activities. ii. Establishment shall be inspected for GMP clearance <p>4. Payment of appropriate fees.</p>
Expansion of Office Establishments and Drug Retailers Shall refer to expansion made which is adjacent to the existing location of the establishment	<ul style="list-style-type: none"> 1. Application Form 2. Current floor plan 3. Expansion floor plan 4. Payment of appropriate fees
Change of Ownership Change only in the business name of the establishment	<ul style="list-style-type: none"> 1. Business name registration reflecting new ownership; 2. Any proof of the transfer of ownership such as any of the following; <ul style="list-style-type: none"> i. deed of sale or assignment or transfer of rights/ownership; ii. memorandum of agreement (MOA); iii. Notarized affidavit of the owner, proprietor, chairman or CEO of the establishment validating the transfer.
Zonal Change in Address Change of the name/number of the street/building without physical transfer of the establishment	<ul style="list-style-type: none"> 1. Application Form 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

	3. Payment of appropriate fees
Change of Qualified Person Change in the identified qualified person initially registered with the FDA	1. Application Form indicating the name of new qualified person 2. Valid PRC ID 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. 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) 4. Payment of appropriate fees.
Change of Authorized Person Change in the authorized person initially registered with the FDA	1. Application Form indicating the name of new authorized person and updated contact details 2. Valid government issued ID 3. Payment of appropriate fees.
Addition/Deletion of Sources and Products Addition/deletion of source(s) and product(s) in the previous/existing list	1. Application Form 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) 3. Payment of appropriate fees.