Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAY 0 8 2020

ADMINISTRATIVE ORDER
No. 2020- 0017

SUBJECT: **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 No. (RA) 11223, otherwise known as the "Universal Health Care Law", and its Implementing Rules and Regulations (IRR) aim to provide a framework that fosters a whole-of-system, whole-of-government, and whole-of-society approach in the development, implementation, monitoring, and evaluation of health policies, programs and plans.

The Food and Drug Administration (FDA) is mandated by RA 9711, otherwise known as the Food and Drug Administration Act of 2009, amending certain provisions of RA. 3720, series of 1963, otherwise known as the Food, Drugs and Devices, and Cosmetic Act to regulate all establishments, namely manufacturers, traders, and distributors (importers, exporters and wholesalers), among others, engaged in business and operations involving health products and to issue product market authorization on all health products prior to manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship.

Further, RA 11032, otherwise known as "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" also aims to promote transparency encompassing a program for the adoption of simplified requirements and procedures to expedite business and non-business related transactions in the government.

Consistent with these laws and the Department of Health (DOH) F1+ Strategic Goals that are geared towards achieving better health for all Filipinos and more responsive health systems by developing innovative regulatory mechanisms for equitable distribution of quality and affordable health goods and services, FDA is currently undertaking efforts to streamline its processes and requirements and to automate and reengineer its systems.

In the interest of public health and welfare protection, this Administrative Order is hereby issued repealing Administrative Order No. 2016-0003 entitled "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration".

II. OBJECTIVES

The objectives for issuing this Administrative Order are as follows:

To simplify the requirements and processes for initial, renewal, and variation of License to Operate (LTO) applications; and

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2. To re-engineer and streamline FDA's processes and automate its system in compliance with the provisions of RA 11032 on the maximum prescribed processing time depending on the complexity of the transaction.

III. SCOPE AND COVERAGE

This Order shall be implemented by the following FDA Centers and Offices: Center for Cosmetics Regulation and Research (CCRR), Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR), supported by the Common Service Laboratories (CSL), Field Regulatory Operations Office (FROO), FDA Action Center (FDAC), Policy and Planning Service (PPS), Legal Services Support Center (LSSC) and Administrative and Finance Service (AFS).

The scope of the health products shall include, but not be limited to:

a. Under the CCRR, all cosmetic products, household/urban hazardous substances (HUHS), including household/urban pesticides, and toys and childcare articles;

b. Under the CDRR, all drugs, including vaccines, biologics, veterinary medicines and animal health products, medical gases, traditional medicine, and herbal medicines;

c. Under the CDRRHR, all medical devices, radiation-emitting devices, in-vitro diagnostic device and reagents; refurbished medical devices; equipment or devices used for treating sharps, pathological and infectious waste, water treatment devices/systems; and other health-related devices as determined by the FDA; and

d. Under the CFRR, all processed food products, food supplements, raw materials, ingredients and additives for food.

Further inclusion of health products in the list shall be guided by RA 9711 on the definition of health products.

The following establishments, whether public or private, shall also be covered by this Order:

a. Manufacturers, including packers/repackers, and refurbisher, as applicable;
b. Traders;
c. Distributors as importers, exporters, and/or wholesalers;
d. Drug outlets, such as drugstores, pharmacies (community, hospital or institutional); or *boticas,* and retail outlets for non-prescription drugs (RONPD);
e. Retailers of Medical Devices
f. Outlets for vapor products, Heated Tobacco Products (HTPs), and similar products;
g. Installer of water treatment systems providing installation, repair and maintenance services to operators of water refilling stations and other users of water treatment systems; and
h. Clinical Research Organizations and clinical trial principal investigator.

The following shall not be covered by this Order:

a. Organizers of national and international trade fairs and exhibits;

b. Donors, organizations or persons involved in donations, medical missions and other humanitarian activities;
c. Manufacturers, traders, or distributors of collector's items;
d. Retailers of cosmetics and household/urban hazardous substances, including household/urban pesticides and toys and childcare articles;
e. Groceries and supermarkets, slaughterhouses or abattoirs, dressing plants, fish ports, wet markets, supermarkets, school canteens, fast foods, restaurants, kiosks, caterers, chandlers, convenience stores, and the likes; and
f. Facilities covered by the DOH One Stop Shop Licensing System.

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

a. Salt manufacturers and distributors shall follow RA 8172 (ASIN Law) and its revised IRR;
b. Bottled water manufacturers and distributors shall follow Administrative Order No. 18-A s. 1993;
c. Radiation facilities;
d. Electronic nicotine/non-nicotine delivery system (ENDS/ENNDS) and HTPs;
e. Operators of pest control for non-agricultural purposes;
f. Applicators of household/urban pesticides and their training providers; and
g. 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. However, the following terms are hereby defined for greater clarity:

1. **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.

2. **Initial Application** or **Original Application** refers to the License to Operate (LTO) applied to FDA prior to engaging in the business or operation involving the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

3. **Packer/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.

4. **Qualified Person** refers to an organic or full-time employee of the establishment who possess 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 or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA

officials when conducting inspection or post-market surveillance activities. The qualified person may also be the duly Authorized Person of the establishment.

5. **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)

6. **Risk Management Plan** refers to the document that contains the details on how to identify, characterize, prevent or minimize the risk relating to the products that the establishment is engaged in. It shall include post-market surveillance activities and interventions to manage identified risks.

7. **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 need only describe those operations, e.g. analysis, packaging, etc.

V. GENERAL GUIDELINES

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

2. All establishments shall have a Qualified Person as defined in this issuance.

3. All establishments, except manufacturing plant or facilities, shall not require pre-licensing inspection. Inspection shall be done after the issuance of the LTO (post-licensing approval).

4. The FDA shall have the authority to enter any FDA-licensed establishments and establishments selling FDA-regulated health products during operating hours to conduct routine or spot check inspections. It is the responsibility of the licensed establishments to immediately recall, withdraw or remove health products from the market that is banned or declared injurious, unsafe or dangerous by the FDA or products or batches of product that have been found to pose imminent danger to public health or consumer safety.

5. All establishments shall provide the appropriate storage condition to maintain the safety and quality of health products.

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

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

8. For drug establishments:
   a. All drug establishments, including drugstores, whether privately owned or government-owned, shall be under the supervision of a registered pharmacist when operating or open for business, unless otherwise allowed by other pertinent laws or regulations.
   b. All FDA-required information, education, and communication campaign materials shall be displayed in the establishment's conspicuous area.
   c. Retailers carrying solely medical devices shall apply for an LTO as Retailer for Medical Devices.

9. For Cosmetic/HUHS establishments:
   a. All establishments engaged in the compounding/mixing of Cosmetic/HUHS products shall secure an LTO as Cosmetic/HUHS Manufacturer. (eg. Customized lipstick)
   b. All licensed Cosmetic/HUHS establishments with refilling activity should only be applied to a Cosmetic/HUHS manufacturer.
   c. All Cosmetic/HUHS establishment applying for an initial application as a manufacturer should declare the refilling activity if applicable. On the other hand, all Cosmetic/HUHS manufacturer with existing LTO should apply a variation application to add refilling activity, if applicable.

10. Qualified Person in Industry Regulatory Affairs (QPIRA) certificates shall no longer be required in order to transact business with FDA, or as a condition or requirement to approve LTOs and other authorizations.

11. This Order shall be reviewed by the FDA within three (3) years of implementation.

VI. SPECIFIC GUIDELINES

1. The requirements for applying for LTO shall be as follows:

   A. Initial LTO
      1) Accomplished e-Application Form with Declaration of Undertaking
      2) Proof of Business Name Registration;
      3) Proof of Income (Latest Audited Financial Statement with Balance Sheet); and
      4) Payment of Fees

   B. Renewal of LTO
      1) Accomplished e-Application Form with Declaration of Undertaking; and
      2) Payment of Fees

C. Variation
   1) Accomplished e-Application Form with Declaration of Undertaking;
   2) Documentary requirements depending on the variation or circumstances of the establishment or the product as shown in Annex C of this Order; and
   3) Payment of Fees

D. 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:

   1) Risk Management Plan (RMP), which shall be required for medium and large food manufacturers, and all drug, cosmetics, HUHS, including household/urban pesticides (HUP) and toys and childcare articles (TCCA), medical device manufacturers, traders, and distributors (importer, exporter and/or wholesaler), among others.
   2) Site Master File (SMF), which shall be required for applicants applying for LTO as manufacturers of drugs (CDRR), cosmetic, household/urban hazardous substances, including household/urban pesticides and toys and childcare articles, (CCRR), medical device manufacturers (CDRRHR), and large and medium food manufacturers (CFRR), among others.

Guidance for the above requirements is attached as Annex A.

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

A. Filing of applications

   1) All establishments applying for initial, renewal, or variation shall submit their application through the FDA E-Service Portal System.

      Online transaction shall not be entrusted to a person who is not the duly authorized person since valid applications should be owned by the licensed establishment or the owner/President/CEO. For emphasis, 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.

   2) An evaluator/assessor from the concerned FDA Center shall conduct a pre-assessment on the submitted application and documentary requirements with regards to its completeness. Incomplete submission will not be accepted and the application will not proceed to the next step of the process.

   3) For applications with complete documentary requirements and payment, the FDA shall issue an Acknowledgement Receipt containing the name of the employee who received the application, reference number, agency logo, the date and time of application, payment, and the statement of completeness of the documents submitted. An application is considered filed once the applicant receives the Acknowledgement Receipt.

4) Application for renewal shall be done within three (3) months prior to the validity date of the LTO. Applications filed after the validity date of the LTO shall be subject to surcharge as prescribed in RA 9711 and its IRR.

5) No application for variation of LTO shall be done when an establishment has a pending application for renewal of LTO, or vice versa.

B. Payment

Payment of prescribed fees as indicated in the Order of Payment may be done through the FDA Cashier or the bank (i.e. Landbank of the Philippines, Development Bank of the Philippines, Bancnet) based on the existing FDA issuances. Incomplete payment will not be accepted and the application will not proceed to the next step of the process.

C. Evaluation

1) The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.
2) Any of the following or similar instances shall be a ground for disapproval:
   a. The documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;
   b. The applicant made misrepresentations, false entries, or withhold any relevant data contrary to the provisions of the law or appropriate standards;
   c. The owner has violated any of the terms and conditions of its license; and
   d. Such other analogous grounds or causes as determined by the FDA.
3) The action on the application shall be Approval or Disapproval as provided by RA No. 11032.
4) Automatic renewal as provided for by the IRR of RA No. 11032, specifically Rule VIII. Section 1. *On When Shall Automatic Approval of an Original Application or Request be Granted*, shall apply.
5) Evaluation shall be done within the prescribed working days and office hours. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.

D. Inspection

1) Pre-LTO inspection of facility shall be mandatory for all manufacturers applying for LTO. Other covered establishments shall be inspected by FDA at any time within the validity of its license as part of its post-licensing inspection and post-marketing surveillance activities.
2) All establishments shall not have a virtual office. Absence of physical office upon inspection, without permission or approval from the FDA shall be a ground for disapproval of application or revocation of LTO.

E. Checking of Application Status

The status of the application may be checked or viewed by the applicant through the eServices Portal System. The FDA shall also send the status of the LTO application through the registered email of the applicant.

F. Releasing of LTO

The FDA shall send the approved LTO to the registered email of the applicant. The applicant may also access the approved LTO through the eService Portal System in the FDA website.

3. The validity of LTOs and the applicable fees and other charges shall be covered by the latest FDA issuance.

4. An LTO may be cancelled through the following:

   A. Automatic cancellation if the establishment failed to file an application for renewal after one-hundred twenty (120) days from the date of expiration;
   B. Imposed by the FDA as a penalty, if warranted; and
   C. Voluntary filing through a formal notification with the FDA.

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

5. The FDA shall develop and implement a fully automated online LTO application system within six (6) months after effectivity of this Order.

6. The FDA shall develop a business continuity plan/procedure in case of events of *force majeure* within 12 months after the effectivity of this Order.

VII. PENALTY CLAUSE

Sanctions over violations of any of the provisions of this Administrative Order shall follow the Rules of Administrative Procedure provided in the IRR of RA 9711.

VIII. REPEALING CLAUSE

All issuances, or parts thereof, pertaining to LTO applications covered by this Administrative Order are hereby repealed, including AO 2016-0003 entitled "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration" and Memorandum Circular No. 15 s. 90 "Exemption From The Requirement Providing One Pharmacist For Each Licensed Activity".

IX. 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.

X. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation and upon filing at the Office of the National Administrative Register (ONAR) at the UP Law Center, Diliman Quezon City.

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Secretary of Health

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ANNEX A

Requirements for License to Operate

1. **Application Form**
   Among other information, the applicant shall provide the following information:
   a. Location Plan
   b. Global Positioning System (GPS) coordinates
   c. 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 Authority and Articles of Cooperation; or
   d. For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.

3. **When the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).**

4. **Proof of Income**
   Proof of Income such as latest audited Financial Statement with Balance Sheet (in pdf) shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees.

ANNEX B

Qualified Person Qualification and Credential Requirements

Type of Establishment	Qualified Person	Qualifications/ Requirements
CDRR Drug Manufacturer, Trader and Distributor (wholesaler, importer, exporter), and drug outlet, RONPD	Registered Pharmacists (RA 10918)	a. Professional Regulatory Commission (PRC) Identification Card (ID) b. Certificate of Attendance to seminars, training, 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
CFRR Food Manufacturer, Trader and Distributor (wholesaler, importer, exporter)	Company Regulatory Officer (Authorized Person) and Food Safety Compliance Officer who is 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).	Certificate of Attendance on seminar on food safety, GMP or HACCP given by the academe, WHO, FAO, NGOs, cooperative, food industry organizations, professional organizations, or the FDA Academy

CDRRHR Manufacturer, Trader and Distributor (wholesaler, importer, exporter) of: • medical devices, • radiation-emitting devices, • in-vitro diagnostic device and reagents; • refurbished medical devices; • equipment or devices used for treating sharps, pathological and infectious waste, • water treatment devices/systems; and • other health-related devices	Registered professional or graduates in the field of allied health profession: Pharmacy, Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Physical Therapy and other allied science courses relevant to the device to be distributed, imported or manufactured: Engineering (includes the following course but not limited to EE, ECE, ME, CoE, CHE, SE), Computer Science, and Chemistry.	a. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam b. Certificate of Attendance to seminars, training, learning and development activities on medical device safety, quality and use given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organization, like the WHO and ISO
CCRR Manufacturer, trader and distributor (wholesaler, importer, exporter) of : • Cosmetics Establishments	Registered professional or graduates in the field of allied health profession. For Manufacturers only: Registered Chemist, Chemical Engineer and Pharmacist	a. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam b. Certificate of Attendance to seminars, training, learning and development activities on cosmetic, HUHS/HUP or TCCA safety, quality and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organization, like the WHO and ISO, including seminar conducted by the FDA Academy for QPIRA
• Household/ Urban Hazardous Substances Establishments	HUHS - any licensed Allied Health Professional HUP – Qualification relevant to the following fields: Pharmacy, Chemistry, Chemical Engineering,	c. PRC ID for professions with Board/ Licensure Exam or Diploma for profession without Board/ Licensure Exam Certificate of Attendance to

	Toxicology, Veterinary Medicine, Agricultural Biotechnology (Entomology) and Entomology. TCCA – Bachelor's Degree	seminars, training, learning and development activities on cosmetic, HUHS, HUP, or TCCA safety, quality and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organization, like the WHO and ISO, including seminar conducted by the FDA Academy for QPIRA

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
Transfer of Location of Manufacturing Plant - Physical transfer of the establishment (and may entail changes in the previously approved address)	a. Business permit reflecting the new address b. Updated Site Master File to be presented upon inspection
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Expansion shall refer to expansion made which is adjacent to the existing location of the establishment - Additional product line refer to additional type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.) - Change in manufacturing activity shall refer to an additional activity that a manufacturer engage in (e.g. LTO as Manufacturer with additional activity as Repacker)	Updated Site Master File to be presented upon inspection

2. Minor Variation

Transfer of Location of Offices - Physical transfer of the office of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new location office
Transfer of Location of Drug Retailers - Physical transfer of the drug retailer (which may also entail changes in the previously approved address)	Business permit reflecting new address
Change of Distributor Activity - Shall refer to an additional/deletion of/change inactivity that the distributor engage in	Contract Agreements showing change in activity
Transfer/Addition of Warehouse - Physical transfer and addition of the warehouse of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new warehouse

Additional Drugstore Activities	a. Additional Credentials of Pharmacist, as applicable b. Other documents related or specific to the additional activity, such as but not limited to: • Adult Vaccination - Standard Operating Procedure • Dispense Vaccines and Biologicals - Standard Operating Procedure • Mobile Pharmacy – Standard Operating Procedure • Online Ordering and Delivery - Standard Operating Procedure and Website Screenshot • Sterile Compounding and Non-Sterile Complex Compounding - Standard Operating Procedure • Other additional activities that may be require appropriate regulation.
Expansion of Office Establishments and Drug Retailers - Shall refer to expansion made which is adjacent to the existing location of the establishment	Expansion floor plan
Change of Ownership - Change in ownership of the licensed establishment	a. Business name registration reflecting new ownership b. Any proof on the transfer of ownership such as any of the following: i. Deed of sale or assignment or transfer of rights/ownership; ii. Memorandum of Agreement; or iii. Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer
Change of Business Name - Change only in the business name of the establishment	Business permit reflecting the new name
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	Certificate of Zonal Change
Change of Qualified Person - Change in the identified qualified person initially registered with the FDA	a. Name of new qualified person b. Applicable requirements as specified in Annex B
Change of Authorized Person - Change in the authorized person initially registered with the FDA	a. Name of new qualified person b. Updated contact details