



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

FEB 15 2016

ADMINISTRATIVE ORDER

No. 2016-0003

SUBJECT: Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)

I. RATIONALE

The 1987 Philippine Constitution mandates the establishment of an effective food and drug regulatory system that is responsive to the country's health needs and problems.

Consistent with said constitutional provision, Congress passed landmark legislations, namely Republic Act (RA) No. 3720 (Food, Drugs and Devices and Cosmetics Act), as amended by RA No. 9711 (Food and Drug Administration Act of 2009), RA No. 10611 (Food Safety Act of 2013), and RA No. 9502 (Universally Accessible Cheaper and Quality Medicine Act of 2008) mandating FDA to regulate establishments engaged in health products to ensure consumer safety, welfare protection, and fair trade practice.

In order to improve FDA's effectiveness and efficiency in carrying out its mandate, there is a need to harmonize, unify and streamline its processes and licensing requirements. This will help ensure the availability and accessibility of quality and safe health products in the market.

II. OBJECTIVES

This Order sets the guidelines on a unified, harmonized and streamlined licensing requirements of the Food and Drug Administration to hasten its approval process and strengthen its post-marketing surveillance activities.

III. SCOPE

This Order shall apply to the four (4) FDA Centers – namely, Center for Cosmetics Regulation and Research (CCRR), Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR), Center for Device Regulation, Radiation Health and Research (CDRRHR) – and the Field Regulation Operations Office (FROO).

These guidelines shall cover, the following establishments, whether public or private:



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1. Manufacturers, traders and distributors (importers, exporters, and wholesalers) of processed foods, drugs (including vaccine, biologics, veterinary drugs and products), cosmetics, medical devices, in-vitro diagnostic device and reagents, household/urban pesticides, toys, and child care articles; and
2. Drugstores/pharmacies/boticas (including hospital pharmacies and institutional pharmacies), and retail outlets for non-prescription drugs (RONPD).

However, it shall not apply to or cover the following establishments or persons as these are not currently required to secure LTO prior to commencement of their business activity:

1. Retailers or retail outlets of food, cosmetics, medical devices, in-vitro diagnostic devices and reagents and household/urban hazardous substances, toys and child care articles;
2. Operators or applicators of household or urban pesticides;
3. Organizers of national and international trade fairs and exhibits;
4. Organizations or persons engaged in donations, medical missions and other humanitarian activities; and
5. Importers/ Distributors of collector's items

Finally, the application for LTO of the following establishments or persons shall be governed by separate rules and regulations:

1. Sponsors and contract research organizations (CROs) shall comply with Administrative Order No. 2014-0034 and FDA Circular No. 2015-003;
2. Facilities using medical and non-medical radiation devices;
3. Salt manufacturers and distributors governed by RA 8172 (ASIN Law); and
4. Bottled water manufacturer and distributor shall comply with Administrative Order No. 18-A s 1993.

IV. GENERAL GUIDELINES

- A. The terms used in this AO shall have the meaning as defined in RA 9711 and its IRR, and related laws and regulation.
- B. All establishments covered in this AO shall first secure the appropriate LTO or authorization from FDA prior to engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertisement and/or sponsorship of any activity that involves health product.
- C. All licensed manufacturers are granted an Initial LTO based on the minimum requirements set by FDA in order to operate a manufacturing plant. A Certificate of GMP Compliance shall only be issued upon demonstration of satisfactory compliance to GMP and effective up to the validity of the current LTO. Thereafter, the Certificate of GMP Compliance shall be issued each time the LTO is renewed.
- D. All covered establishments must continuously comply with the existing requirements, regulations and standards, otherwise they may be ordered closed or their licenses be suspended or revoked *motu proprio*, or upon petition by any affected person. A violation with any of the terms and



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conditions of the LTO may result in the suspension, revocation or cancellation of the LTO, or disapproval of its application for renewal.

- E. All covered establishments shall be under the supervision of a qualified person(s) as required by pertinent rules and regulations (refer to Annex A).
- F. The FDA shall have the authority to enter any covered establishment for (1) inspection and/or (2) verification of documents submitted to FDA in support of its application for license.
- G. The responsibility of ensuring the safety, quality, and when applicable, the efficacy and/or purity of health products, shall rest upon all the establishments or persons involved in the production, sale, handling, packing, transport, distribution, trading and storage thereof.

V. SPECIFIC GUIDELINES

- A. 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 from the public its sale, distribution or donation, or its immediate recall, withdrawal or seizure from the market.
- B. Establishments engaged in health product that is declared by FDA to be injurious, unsafe or dangerous are required to immediately recall, withdraw, or seize the product, or ban its sale, distribution or donation to the public.
- C. For drug establishments:
 - 1. All drug establishments engaged with vaccines, biologics and other temperature-sensitive drug products shall comply with the cold chain management requirements.
 - 2. All 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.
 - 3. All FDA-required information, education and communication campaign material shall be displayed in the establishment's conspicuous area.
- D. All approved LTO applications shall be sent through courier directly to the establishment's owner, president, CEO, general manager or equivalent responsible officer as indicated in the application form.

VI. PROCEDURE

A. Application Requirements

The following are the requirements for application of a License to Operate (LTO).

1. Initial Application



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- (a) Accomplished Application Form and Declaration and Undertaking
- (b) Proof of Business Name Registration
- (c) Site Master File (for manufacturers of drugs, devices and cosmetics)
- (d) Risk Management Plan
- (e) Payment

2. Renewal Application

- (a) Accomplished Application Form with Declaration and Undertaking
- (b) Payment

Guidance for the above requirements is attached as Annex "A".

B. Application Process

1. Filing

An application for LTO, whether initial, renewal, or variation, and other authorizations are deemed filed upon submission of complete requirements including payment of required fees and charges.

2. Evaluation

The evaluation of all applications for LTO shall be based on the veracity of the submitted documents and compliance with appropriate standards.

In case the applicant falsified, misrepresented material facts or documents, or withheld any material data or information, the application shall be disapproved. In such cases, the applicant may be investigated, appropriate charges may be filed, and penalties may be imposed.

Should there be a need for clarification on the application, a notification, either written or through e-mail, shall be sent to the applicant.

3. Inspection

Pre-opening inspection shall be mandatory for manufacturers. All covered establishments may be inspected at any time by FDA as part of its post-marketing surveillance activities.

C. Variations

Variations shall require prior FDA approval. Variations may either be major or minor.



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1. Major variation covers changes in the operations of the establishment that may affect significantly and/or directly the aspects of safety and quality and when applicable, efficacy of products.

Major variation shall only be approved upon proper notification, compliance to requirements and inspection.

2. Minor variation covers changes in administrative matters and/or changes in the operations of the establishment but with minimal impact on the safety, quality and, when applicable, the efficacy of products.

The list of variations, the conditions, and the documentary requirements is attached as Annex "B".

The FDA Director-General may issue orders to categorize certain variations which are not included in the enumeration as either major or minor variation.

D. Validity and Fees

The validity of LTOs and the applicable fees and other charges shall be covered by separate issuances.

E. Cancellation of License to Operate

1. Automatic. Existing establishments that fail to file an application for renewal after one-hundred twenty (120) days from the date of expiration shall be automatically cancelled and deleted from the list of licensed establishments without prejudice to their re-application.
2. Voluntary. The owner or authorized person of a licensed establishment may apply for voluntary cancellation of its existing license by filing a formal notification with the FDA.
3. Cancellation as a Penalty. The FDA may also impose the penalty of cancellation of license.
4. 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. All establishments shall settle all their monetary obligations to FDA.

F. Accessibility

The relevant forms, requirements for application, and the submission process shall be made accessible at the FDA Website.



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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 implementing rules and regulations of Republic Act No. 9711.

VIII. REPEALING CLAUSE

All issuances, or parts thereof, pertaining to LTO applications covered by this Administrative Order are hereby repealed.

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.

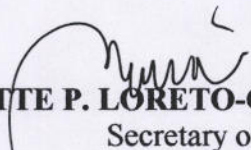
X. MANDATORY REVIEW

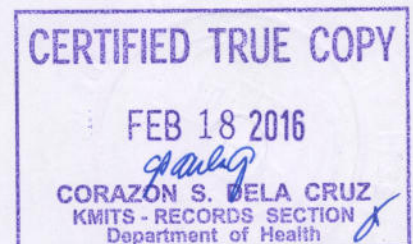
This Administrative Order shall be reviewed by FDA after two (2) years of its implementation.

XI. EFFECTIVITY

This Administrative Order shall take effect on 01 March 2016 following its publication in 2 newspapers of national circulation and submission to the University of the Philippines Law Center.

For drugstores and RONPDs, mandatory submission of RMP will be effective on January 1, 2017.


JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health



ANNEX A
Guidance LTO Application

A. The establishment's owner, president, chief executive officer (CEO) or authorized officer and its qualified person shall sign the application form. The authority of the signatories shall be evidenced by any of the following:

1. Single Proprietorship – Power of Attorney when the authorized representative is not the owner of the establishment;
2. Corporation and Cooperative – Secretary Certificate or Board Resolution;
3. Partnership – Partnership Resolution; or
4. Government Agency – Authority from the Head of Agency.

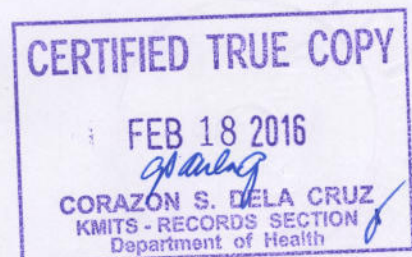
B. The documentary requirements for submission:

1. Accomplished Application Form

Among other information, the application form shall contain the following:

- (a) Declaration and undertaking of the responsibilities of the applicant as a condition for the processing and approval of the LTO;
- (b) The location plan and global position system (GPS) coordinates of the establishment;
- (c) The name of the qualified person per type of establishment, and the relevant credentials (e.g. PRC ID):

Type of Establishment	Qualified Person	Credentials
Drug Establishment:	Pharmacist	<input type="checkbox"/> PRC ID <input type="checkbox"/> Attendance to FDA appropriate Licensing Seminar
	Responsible pharmacy assistant (for drugstore and RONPDs)	<input type="checkbox"/> Certificate of Training
Food Establishment	Food Safety Compliance Officer or Regulatory Officer	<input type="checkbox"/> Certificate of Attendance to appropriate FDA Licensing Seminar <input type="checkbox"/> Certificate of Attendance to GMP, HACCP, or Food Safety Seminar
Medical Device Establishment	Pharmacist or Any Other Qualified Professional	<input type="checkbox"/> PRC ID or any Proof of Qualification <input type="checkbox"/> Attendance to medical device QPIRA
Cosmetic Establishment	Pharmacist or Any Other Qualified Professional	<input type="checkbox"/> PRC ID or any Proof of Qualification <input type="checkbox"/> Attendance to QPIRA



(d) The names of the following personnel shall also be listed:

Type of Establishment	Other Qualified Person
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
Other Drug Establishments	(a) 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 Establishment	(a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head
Cosmetic Establishment	(a) Production Manager/Head (b) Quality Control and/or Assurance Manager/Head

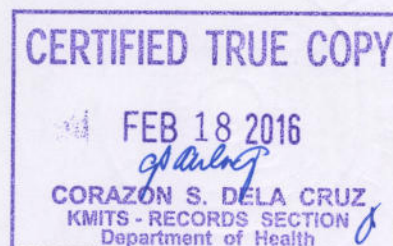
2. Proof of Business Name Registration

The business name/registration must be evidenced by copies of the following:

- (a) For single proprietorship – Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
- (b) For corporation, partnership and other juridical person – Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;
- (c) For cooperative – Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or
- (d) For government-owned or controlled corporation – the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.

The document must indicate the exact and complete address, e.g., unit number, floor, building, lot, block, phase, street, barangay, city/ municipality, province, where applicable.

In case the business address of the applicant is different from the one indicated in its business name registration, the applicant must submit a copy of its valid Business Permit.



3. Site Master File¹ (for manufacturers of drugs, devices and cosmetics except traders)

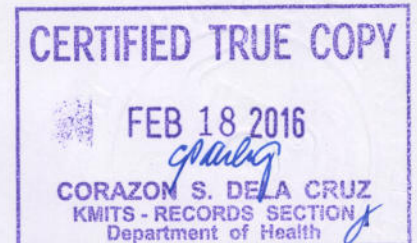
As required by the applicable good manufacturing practice (GMP) for the type of establishment.

4. Risk Management Plan (for manufacturers and distributors of drugs and medical devices establishments, and drugstores and RONPDs)

A general Risk Management Plan (RMP) for the establishment must be submitted. The RMP shall contain details on how to identify, characterize, prevent or minimize risk relating to the products that the establishment is engage with. These shall include post-marketing surveillance activities and interventions to manage the risks.

5. Payment

Proof of payments (e.g., official receipt or authorized bank payment slip) must be attached to the application.



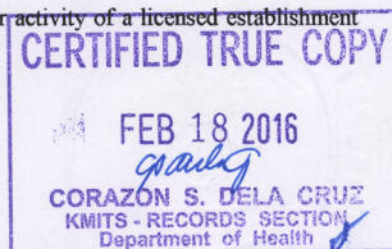
¹ Site Master File refers to a document prepared by the manufacturer and contains specific information about the quality management policies and activities of the site, the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. It provides clear information on the manufacturer's GMP related activities that are useful in general supervision and in the efficient planning and undertaking of GMP inspections.

ANNEX B
LIST OF REQUIREMENTS FOR VARIATION
APPLICATIONS FOR ESTABLISHMENTS

A. Major Variation²

Transfer of Location of Manufacturing Plant and Drug Retailers	
C	<ol style="list-style-type: none"> 1. Physical transfer of the establishment (and may entail changes in the previously approved address). 2. Other variations (e.g. change of pharmacist or qualified personnel, and/or business name) may also be included in the application for variation provided that that same are indicated therein and the corresponding requirements for such changes are included.
D	<ol style="list-style-type: none"> 1. Application Form 2. Business permit reflecting the new address 3. Updated Site Master File 4. Payment
Expansion of Manufacturer	
C	<ol style="list-style-type: none"> 1. Shall refer only to the expansion made which is adjacent to the existing location of the establishment and no additional product line is involved. 2. Expansion shall also include additional floors for production.
D	<ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File 3. Payment
Additional Production Line	
C	An additional production line is an added type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.)
D	<ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File 3. Payment
Change of Manufacturing Activity	
C	<ol style="list-style-type: none"> 1. Shall refer to an additional activity that the manufacturer engages in (e.g. LTO as Manufacturer with additional activity as Repacker) 2. Shall also refer to a change of previously licensed activity (e.g. LTO as Manufacturer-Repacker to Manufacturer-Packer).

² Major variation refers to post-FDA approval changes in the status, condition or activity of a licensed establishment where inspection is required prior to approval of variation.



D	<ol style="list-style-type: none"> 1. Application Form 2. Updated Site Master File 3. Payment
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Transfer/Addition of Warehouse	
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C	<ol style="list-style-type: none"> 1. Shall refer to the physical transfer of warehouse. 2. Shall also refer to an addition of warehouse aside from the existing and previously inspected warehouse by FDA.
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D	<ol style="list-style-type: none"> 1. Application Form 2. Business permit reflecting new warehouse 3. Payment
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B. Minor Variation ³

Transfer of Location of Offices	
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C	<ol style="list-style-type: none"> 1. Physical transfer of the office of the establishment (which may also entail changes in the previously approved address). 2. Other variations (e.g. change of pharmacist or key personnel, and/or business name) may also be included in the application for variation provided that that same are indicated therein and the corresponding requirements for such changes are included.
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D	<ol style="list-style-type: none"> 1. Application Form 2. Business permit reflecting the new address 3. Payment
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Change of Distributor Activity	
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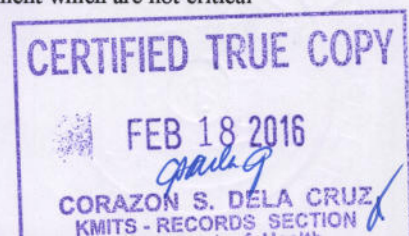
C	<ol style="list-style-type: none"> 1. Shall refer to an additional activity that the distributor engages in (e.g. LTO as Distributor-Importer with additional activity as Exporter) 2. Shall also refer to a change from the initially licensed activity (e.g. LTO as Distributor-Importer to Distributor-Exporter).
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D	<ol style="list-style-type: none"> 1. Application Form 2. Contract Agreements to prove activity 3. Payment
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Expansion of Office Establishments and Drug Retailers	
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C	<ol style="list-style-type: none"> 1. Shall refer to the expansion made which is adjacent to the existing location of the establishment. 2. Expansion shall also include additional floors where the building is occupied.
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³ Minor variation refers to changes in the status, condition or activity of a licensed establishment which are not critical to the safety or quality, or in the purity or efficacy, when applicable, of the health product.



D	1. Application Form 2. Payment
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Additional Drugstore Activity

C	1. Additional activity shall include online ordering and delivery, sterile compounding and non-sterile complex compounding, mobile pharmacy, carrying of medical devices, and other additional activities that may require appropriate regulation or may be handled on a case to case basis. 2. These additional activities may already be included in the initial application.
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D	1. Application Form 2. Additional Credentials of Pharmacist (e.g. Certificate of Training, where applicable) 3. Documents related to activity with proof of validation (e.g. SOP, Masterlist of compounding recipes) 4. Payment
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Change of Ownership

C	There is a change of ownership of the licensed establishment.
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D	1. Application Form 2. Any proof on the transfer of ownership such as any of the following: Deed of sale or assignment or transfer of rights/ownership, Memorandum of Agreement, or notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer 3. Payment
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Change of Business Name

C	1. Change only in the business name 2. No transfer of location or change of ownership.
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D	1. Application Form 2. Proof of business name registration reflecting the new name
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Zonal Change in Address

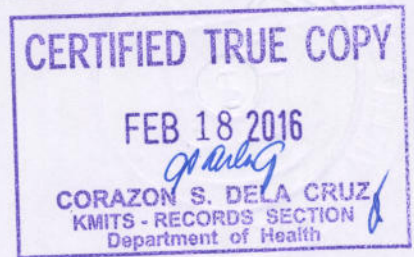
C	Shall refer to change of the name/number of the street/building without physical transfer of the establishment.
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D	1. Application Form 2. Payment
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Change of Qualified Personnel

C	There is a change of the identified qualified person registered with FDA
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D	1. Application Form 2. Payment
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Deletion of Activity	
C	Shall refer to deletion of any approved/added activity.
D	<ol style="list-style-type: none"> 1. Application Form 2. Payment

* C - Condition

** D - Documentary Requirements

