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:

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

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

(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.

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.

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

CERTIFIED TRUE COPY
FEB 18 2016
CORAZON S. DELA CRUZ
KMITS - RECORDS SECTION
Department of Health