



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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