Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

07 JUN 2016

FDA CIRCULAR
No. 2016-006

TO : **ALL ESTABLISHMENTS REGULATED BY THE FOOD AND DRUG ADMINISTRATION (FDA) AND OTHER CONCERNED STAKEHOLDERS**

SUBJECT: **New Format of License to Operate (LTO) for Establishments Regulated by the FDA**

1. BACKGROUND

Part of the continuous quality improvement activities of the Food and Drug Administration (FDA) as an ISO certified institution is to enhance, upgrade and strengthen its processes by establishing an effective and efficient Quality Management System (QMS) in place. The FDA has streamlined its requirements for ease of doing business and improved the quality of its services in order to address the needs of its clients.

With the issuance of Administrative Order (A.O.) No. 2016-0003 entitled "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration," a new LTO format for establishments regulated by the FDA is deemed necessary.

2. DETAILS

2.1. LICENSE TO OPERATE

The LTO shall reflect the following information :

2.1.1. The **first page** of the new LTO format shall reflect only the following data:
- 2.1.1.1. Type of application
- 2.1.1.2. Primary activity(ies)
- 2.1.1.3. Name of establishment
- 2.1.1.4. Address of the establishment
- 2.1.1.5. Name of owner
- 2.1.1.6. LTO number and validity
- 2.1.1.7. Payment details (date and amount)

2.1.2. The **second page** of the new LTO format shall contain the minimum data:

2.1.2.1. For drugs manufacturers, list of key personnel (e.g., quality control/quality assurance manager, production head, pharmacist (whenever applicable) and authorized person for product batch release) in accordance with the requirements of current regulations on Good Manufacturing Practices (GMP) ; and

2.1.2.2. Additional activity(ies) (whenever applicable)

2.1.3. The second page should be made readily available upon request by stakeholders and authorities.

2.1.4. A new LTO shall be issued incorporating any variation to the original LTO, regardless of its validity.

3. REPEALING CLAUSE

This Circular repeals any inconsistent previous issuance, including FDA Circular No. 2015-006 known as "New LTO Format for Drug Establishments Following Administrative Order No. 2013-0034."

4. EFFECTIVITY

This Circular shall take effect immediately.

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OIC, Director General