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REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS
MANILA 1099

June 16, 2016

CUSTOMS MEMORANDUM CIRCULAR NO. 84 - 2016

TO: All Deputy Commissioners
All Directors and Division Chiefs
All District / Port Collectors
And Others Concerned

SUBJECT: **FDA Circular No. 2016-006 / *New Format of License to Operate (LTO) for Establishments Regulated by the FDA***

Attached is the letter dated June 7, 2016 of Ms. Maria Lourdes C. Santiago, MSc., MM, OIC-Director General, Food and Drug Administration (FDA), furnishing this Bureau with a copy of FDA Circular No. 2016-006 entitled: "New Format of License to Operate (LTO) for Establishments Regulated by the FDA"

For your information and guidance.

Please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt hereof.

ALBERTO D. LINA
Commissioner

Bureau of Customs
ALBERTO D. LINA
Commissioner
16-03580
JUN 20 2016

06-002

CMC 84-2014, P.2

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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA III
Food and Drug Administration PHILIPPINES

07 June 2016

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BUREAU OF CUSTOMS
Office of the Commissioner
Incoming Document No.
16-17961

Mr. ALBERTO D. LINA
Commissioner
Bureau of Customs
G/F, OCOM Building
Port Area, Manila

Dear Commissioner Lina :

Warm greetings from the Food and Drug Administration (FDA) !

The FDA is pleased to inform your good office of the new format of License To Operate (LTO) we will soon use. The LTO will contain essential information on the first and second pages to align with the provisions of FDA Circular No. 2016-006, *"New Format of License To Operate (LTO) for Establishments Regulated by the FDA"* (please see attached).

We earnestly request that this guideline be disseminated within your agency for the information, reference and guidance of all concerned.

Thank you for the kind attention and your usual support and cooperation.

Very truly yours,

MARIA LOURDES C. SANTIAGO, MSc., MM
OIC, Director General

Attachment : As stated

06-08

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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:

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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.

MARIA LOURDES C. SANTIAGO, MSc., MM
OIC, Director General