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NEW LTO FORMAT FOR DRUG ESTABLISHMENTS FOLLOWING ADMINISTRATIVE ORDER NO. 2014-0034

FDA Circular No. 2015-006, April 13, 2015

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Adopted: 13 April 2015
Date Filed: 08 May 2015
Following the implementation of Administrative Order No. 2014-0034, Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations, a new License to Operate (LTO) format for drug establishments shall be issued for approved applications effective immediately.

The new LTO format shall reflect only pertinent information (e.g., name and address of establishment, name of owner, LTO number and validity, payment details) of the said establishments. Other information, where applicable:

(1)

names of pharmacist and/or key personnel (e.g., production head, quality control and quality assurance manager, and authorized person to release the batch)

(2)

list of sources (whether imported or locally-manufactured finished pharmaceutical products and/or raw materials

(3)

other activities handled/carried out by a Drug Manufacturer/Trader such as importation of raw materials for own production, importation of finished products for local packing/repacking, exportation of own products; and for a Manufacturer/Packer/Repacker, contracting activity as defined in Administrative Order No. 2014-0034

(4)

list of contract manufacturer/packer/repacker/trader clients as well as its corresponding products

shall no longer be included as an attachment to the LTO but rather will be reflected only in the FDA database. To this effect, only a single-paged LTO shall be issued. For instances wherein a variation application has been approved and a corresponding Certificate has been issued, this Certification shall be considered as an attachment to the LTO until it is renewed.

For further clarification, any changes to the approved LTO of a drug establishment that have not yet been included in the list of variations mentioned in the implementing Circulars of Administrative Order No. 2014-0034 (e.g., addition or deletion of source(s), product(s), and/or activities as stated in #3 above), FDA shall be duly informed/notified through submission of Notification Letter.

For the submission process, two original copies of the Notification Letter must be submitted through the Public

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Assistance, Information and Receiving (PAIR) during office hours without the need for prior appointment schedule.

Upon receipt of PAIR, a Document Tracking Slip (DTS) shall be issued which shall serve as proof of acknowledgement that the Notification has been received and that FDA has been duly notified of the change.

For submissions not covered by PAIR these may be coursed through the respective Regional Offices covering the area. The FDA Supervisor or delegated Officer from each Regional Offices are authorized to receive and sign the Notification Letters which shall serve as proof of acknowledgement of the notification.

A sample notification letter is attached with this Circular and is also available in the FDA website.

Failure to inform FDA of any changes shall be subject to appropriate regulatory action.

This supersedes FDA Memorandum Circular No. 2014-002.

For information and guidance

(SGD) ATTY. NICOLAS B. LUTERO III, CESO III
OIC-Director IV
Food and Drug Administration

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