



21 JUN 2017

FDA CIRCULAR
No. 2017-003

TO: ALL IMPORTERS, DISTRIBUTORS, WHOLESALERS, MANUFACTURERS, TRADERS, REPACKERS OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC MEDICAL DEVICES

SUBJECT: Strict Implementation of the Mandatory Requirement to Secure a License to Operate (LTO), Certificate of Product Registration (CPR) or any authorization from FDA Prior to Engaging in the Manufacture, Importation, Exportation, Sale, Offering for Sale, Distribution, Transfer, Promotion, Advertisement and/or Sponsorship of Medical Devices

I. BACKGROUND

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) mandates Food and Drug Administration (FDA) to regulate establishments engaged in health products to ensure consumer safety, welfare protection, and fair trade practice.

On 25 February 2014, FDA Memorandum Circular No. 2014-005, Updated List of Medical Devices required to be registered prior to sale, distribution and use was issued so as to provide the initial list of medical devices and in-vitro diagnostic medical devices that are required for mandatory registration. Industries which manufacture, import and distribute medical devices that are registrable are required to secure LTO as Medical Device Manufacturer, Importer and/or Distributor. Those industries which manufacture, import and distribute medical devices that are not registrable are exempted from securing the LTO.

However, on 15 February 2016, Administrative Order No. 2016-0003, Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA), was issued requiring all establishments to secure LTO whether the medical devices to be manufactured, imported and distributed are registrable or not registrable.

II. SCOPE AND PURPOSE

This circular clarifies the provisions of Administrative Order No. 2016-0003 to strictly implement the mandatory requirement to secure LTO.



This circular shall cover all medical device industry which includes the Importers, Exporters, Distributors, Wholesalers, Manufacturers, Traders, Repackers of medical devices including in-vitro diagnostic medical devices

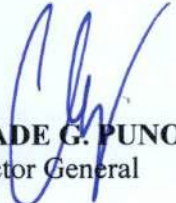
III. DETAILS

In line with the implementation of Administrative Order No. 2016-0003, the following shall be implemented:

1. All establishments covered in this FDA Circular shall first secure the LTO or any appropriate authorization from the Center for Device Regulation, Radiation Health and Research (CDRRHR) prior to engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertisement and/or sponsorship of medical devices including in-vitro diagnostic medical devices.
2. All Importers, Exporters, Distributors, Wholesalers, Manufacturers, Traders, Repackers shall submit notification of sources immediately after the approval of the LTO.
3. Notification of sources shall be submitted to the Public Assistance Information and Receiving (PAIR) Unit following the attached Microsoft Excel format for the updated list of sources (existing and amendments).
4. For any variation, addition of source or deletion of source in the LTO, the establishment is required to file for a new notification.
5. No more LTO exemption shall be issued by the CDRRHR except for establishments who are doing research or for educational purposes.
6. The qualified person for medical device shall refer to the persons who are graduates and passed the board examination (if applicable) of the following courses: Pharmacy, Engineering (EE, ECE, ME, COE, ChE), Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Computer Science, Chemistry, Physical Therapy and any other allied science courses relevant to the device to be distributed, imported or manufactured.

Previous issuances which are inconsistent with those provided in this Circular are hereby rescinded/repealed and/or modified accordingly.

For strict compliance.


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Director General