



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA CIRCULAR**

No. 2016-010

18 JUL 2016

**TO: ALL THE MEDICAL DEVICE INDUSTRY**

**SUBJECT: New Procedures for Filing of Application for Medical Device Product Registration and Medical Device Establishment License**

The office of the Licensing and Registration Division (LRD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR) is transferred from the Department of Health (DOH), Sta. Cruz, Manila to the Food and Drug Administration (FDA), Alabang, Muntinlupa City. The new procedures for filing of application for medical device product registration and licensing of medical device establishments and other certifications shall be implemented by the LRD-CDRRHR starting 19 July 2016.

1. All applications for medical device product registration and licensing of medical device establishments, including but not limited to certificate of exemption, certificate of free sales, notification of sources, and other certifications shall be filed at the FDA Public Assistance, Information, and Receiving (PAIR) Unit.
2. The following schedule shall be followed by the companies in the submission of their applications for a Certificate of Product Registration (CPR), License to Operate (LTO) a medical device establishment, and Certificate of Product Exemption depending on the first letter of the first name of the company:
  - a. A to M – every Monday only
  - b. N to Z – every Friday only

In the event that the name of the company starts with a number, the schedule to be followed will be that of A to M.

3. Submission of applications shall be from 8:00AM to 5:00PM. However, the payment of fees and charges at the Cashier is from 7:00am to 3:00pm, no noon break. Please refer to FDA Memorandum Circular 2012-033-A dated 20 October 2014 for other details, e.g. acceptance of check.



4. The electronic copy of the application document in accordance with the appropriate checklist of requirements shall be stored in a USB device with the following specifications:
  - a. All documents for uploading must be in PDF format, free from bugs, viruses and the like that may jeopardize the system of the FDA ;
  - b. Before uploading, all documents must be scanned and complied with 100-150 dots-per-inch (dpi) ;
  - c. File name of documents for uploading should be less than 40 characters in length and should not contain the following characters  
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5. Hardcopies shall no longer be required upon submission. However, hardcopies of the application shall always be made available and submitted upon request of the CDRRHR in the process of evaluation or during inspection monitoring.
6. The transaction for product registration is limited to a maximum of five (5) applications per company. This may be in combination of any of the following: initial, renewal and amendment application.
7. For Certificate of Exemption, the companies shall file only one application covering all medical devices/equipment to be applied.
8. Submission of compliance documents, including re-application (for CPR) shall be accepted Monday to Friday from 8:00AM to 5:00PM.

The following processes flow shall be followed in receiving the applications during this process of transition:

1. Only applicants scheduled for the specific day for medical devices shall be accommodated.
2. Get queue number from the guard-on-duty.
3. The evaluator of the day reviews the completeness of the application in accordance with the checklist of requirements.
4. If the application is complete and acceptable, the evaluator of the day issues an Order of Payment and Document Tracking Number (DTN).
5. The applicant shall proceed to the Cashier for payment.
6. The applicant shall proceed to the person-in-charge in uploading the application and documents from the USB device.

This FDA Circular shall supersede FDA Memorandum No. 2012-008 and 2012-008-A. Previous issuances which are inconsistent with those provided in this Circular are hereby rescinded/repealed and/or modified accordingly.

This Circular shall take effect on 19 July 2016.

  
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OIC, Director General