Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2016-015

01 AUG 2016

TO : **ALL THE HEALTH RELATED DEVICE AND THE MEDICAL DEVICE INDUSTRY**

SUBJECT : **New Procedures for Filing of Application for Certificate of Health Related Device Registration for Water Purification Equipment and Devices and Certificate of Product Registration (CPR) for Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and Other Authorizations**

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1. BACKGROUND

The office of the Center for Device Regulation, Radiation Health and Research (CDRRHR) was transferred from the Department of Health (DOH), Sta. Cruz Manila to the Food and Drug Administration (FDA), Alabang Muntinlupa City.

In pursuit of transparency and accountability in providing public service, the CDRRHR will adopt the Public Assistance, Information and Receiving (PAIR) Process in the filing and submission of applications for Certificate of Health Related Device Registration for Water Purification Equipment and Devices and Certificate of Product Registration (CPR) for Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and other authorizations.

2. DETAILS

The new procedures for filing of application for health related device product registration and other authorizations shall be implemented by the CDRRHR starting 8 August 2016.

2.1 All applications for health related device product registration and other authorizations such as sales promotion permits, clearance for customs release and other certifications shall be filled at the FDA PAIR Unit.

2.2 The submission of application/s shall be strictly in accordance with the following schedule:

2.2.1 CPR – every **Thursday** only

2.2.2 Sales Promotion Permits – every **Friday** only

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

2.4 In accordance with the appropriate checklist of requirements, the electronic copy of the application document must be stored in a USB device with the following:

2.4.1 All documents for uploading must be in PDF format free from bugs, viruses and the like that may jeopardize the system of the FDA

2.4.2 Before uploading, all documents must be scanned and complied with 100-150 dots-per-inch (dpi)

2.4.3 File name of documents for uploading should be less than 40 characters in length and should not contain the following characters / ? \ : * " >< |

2.5 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.

2.6 Submission of compliance documents shall be accepted Monday – Friday from 8:00 AM to 5:00PM.

2.7 The following process flow shall be followed in receiving the application during this process of transition:

2.7.1 Clients shall be accommodated only on their scheduled day.

2.7.2 Get queue number from the guard-on-duty

2.7.3 The evaluator of the day shall review the completeness of the application in accordance with the checklist of requirements.

2.7.4 If the application is complete and acceptable, the evaluator of the day shall issue an Order of Payment and Document Tracking Number (DTN)

2.7.5 The applicant shall proceed to the Cashier for payment

2.7.6 The applicant shall proceed to the person-in-charge in uploading the application and documents from the USB device.

This Circular shall take effect on 8 August 2016.

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