Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-069

24 JUN 2016

TO : **ALL MEDICAL DEVICE AND HEALTH RELATED DEVICE ESTABLISHMENTS**

SUBJECT : **Center for Device Regulation, Radiation Health, and Research (CDRRHR) Application Holiday from 27 June until 18 July 2016**

The Licensing and Registration Division and the Product Research and Standard Development Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR) will be transferring from Department of Health (DOH) - Manila to the Food and Drug Administration (FDA), Alabang, Muntinlupa City. As such, the period of 27 June 2016 to 18 July 2016 is hereby declared as an **Application Holiday/Moratorium** to give the CDRRHR time to facilitate the transfer of the official documents, office equipment, and transaction processes to their new Office.

For the above-stated purpose, CDRRHR **shall not receive** the following application/document:

1. License to Operate (LTO) as Medical Device Importer, Distributor, Exporter, Trader and Manufacturer (Initial, Renewal and Amendment).
2. Certificate of Product Registration (CPR) for Registrable Medical Devices including In-vitro Diagnostic Kits and Reagents (Initial, Renewal and Amendment).
3. Certificate of Health Related Device Registration for Water Purification Devices/Systems.
4. Certificate of Product Registration for Equipment Used for Treating Sharps, Pathological and Infectious Waste.
5. Certificate of Exemption for Non-Registrable Medical Devices.
6. Certificate of Free Sales.
7. Promo Permit.
8. Extension of the validity of CPR for In-vitro Diagnostic kits and reagents.
9. Compliance documents for both Product Registration and License to Operate.
10. Letters.

As an exception, **only** the herein listed applications shall be entertained following the regular schedule:

1. Non-Radiation Emitting Device Certification.
2. CPR and LTO authentication.

All renewal applications for LTOs and CPRs that are due to expire or compliance that should be received within the moratorium period **shall not be charged** with corresponding penalty/fines or considered disapproved provided that the application are filed or compliance documents are submitted within two weeks after the end of the application holiday.

For the information and compliance of all concerned.

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OIC, Director General