

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2016 - 077 18 JUL 2016

TO:

ALL MEDICAL DEVICE ESTABLISHMENTS

SUBJECT:

Transfer of the Licensing and Registration Division (LRD) and the Product Research and Standard Development Division (PRSDD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR) to the Food and Drug Administration

(FDA), Alabang starting 19 July 2016

Contingent to the transfer of the Licensing and Registration Division (LRD) and Product Research and Standard Development Division (PRSDD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR), all transactions for the registration of medical device products, licensing of medical device establishments, certificate of product exemption, certificate of free sale, promo permits and all other certifications pertaining to the medical devices shall be filed at the Public Assistance, Information, and Receiving Unit (PAIR) of the Food and Drug Administration, Alabang starting 19 July 2016. The new procedures for the filing of application shall be released in a separate FDA Circular.

Meanwhile, releasing of approved Certificate of Product Registration (CPR), License to Operate (LTO), Certificate of Exemption and letters approved prior to 19 July 2016 shall remain at Bldg. 24, Department of Health, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila.

Names of companies with certificates for release shall be posted at the FDA website or shall be informed through email or phone.

Please be guided accordingly.

MARIA LOURDES C. SANTIAGO, MSc, MM OIC, Director General



