

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



24 February 2013

FDA MEMORANDUM CIRCULAR NO. 2013 - 009

## SUBJECT: LTO APPLICATION FOR MEDICAL DEVICES

This pertains to Section 4.2.2.1.3 of the Amended Memorandum Circular No. 2013-001-A which states that "All LTO applications (and its subsequent renewals and/or amendments) for Medical Devices shall be received and processed by the Center for Device Regulation, Radiation, Health and Research (CDRRHR). For clarification purposes, all LTO applications mentioned are LTO applications from Metro Manila or National Capital Region which shall be centrally received and processed by the CDRRHR Manila while application coming from the different provinces outside Metro Manila shall observed the Section 4.2.2.1.2 of the Amended Memorandum Circular which states that "All application from different provinces outside Metro Manila shall be received and processed by the respective Regional Field Office (RFOs) and the Certificate of Compliance (COC)/Reports and other correspondence shall be endorsed and forwarded to different Centers concerned. However, the reports for manufacturers shall be cleared and evaluated for subsequent preparation of COC by NCR-RDO."

For your information and guidance.

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Director General