10 JAN 2024

FDA ADVISORY
No. 20240009

TO: **ALL MEDICAL DEVICE ESTABLISHMENTS APPLYING FOR PRODUCT AUTHORIZATION OF MEDICAL DEVICES**

SUBJECT: **Revision in the Process of Application for Certificate of Medical Device Registration (CMDR)/Certificate of Medical Device Notification (CMDN), Initial and Renewal**

In line with the Food and Drug Administration's objective to improve the processing of CMDR initial and CMDR/CMDN renewal applications, a revision in the process is being implemented.

For all CMDR initial and CMDR/CMDN renewal applications, the applicant company shall be given a "one-time compliance" to secure and submit the deficiencies noted during the review of the application. However, failure to submit the pending compliance documents within the given period, the application shall be considered disapproved.

For a disapproved application, a re-application and full compliance can be made. It shall be complied with within sixty (60) calendar days for the Initial application and thirty (30) calendar days for the Renewal application from the date of disapproval. The re-application will be assigned a new Document Tracking Number (DTN) and will be charged a corresponding fee of PhP 1,010.00, inclusive of the Legal Research Fee (LRF). The re-application shall only include the copy of the NOD and documents to fulfill all the noted deficiencies as cited in the issued NOD.

During the re-application, the applicant shall send an email to fdac@fda.gov.ph with the email subject: REAPPLICATION DTNXXXXXXXXXXXX (old application DTN) for the issuance of the new DTN. Use the new DTN in paying for the re-application fee.

For more information and inquiries, you may send an e-mail to cdrrhr@fda.gov.ph or cdrrhr.lrd@fda.gov.ph

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