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GUIDELINES FOR PAYMENT OF APPLICATIONS WITH THE RADIATION REGULATION DIVISION OF THE CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH

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I. BACKGROUND/RATIONALE

Pursuant to the issuance of FDA Circular No. 2017-010 dated 11 September 2017, the Food and Drug Administration (FDA) implemented a new policy and procedure on collection of payments for applications with the agency. The new policy and procedure allows for expanded payment channels, thereby allowing convenient and efficient transactions.

Consistent with the aforementioned policy, the agency has developed a module on the FDA Payment Portal to cater to clients of the Radiation Regulation Division (RRD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR). The portal aims to integrate previously manually-assessed orders of payment into the new collection system. In line with the implementation of the FDA Payment Portal for applications with the RRD, the following guidelines are hereby provided.

II. OBJECTIVE AND SCOPE

This Circular aims to provide the procedural guidelines for the payment of applications with the RRD assessed through the FDA Payment Portal. These guidelines shall apply to all radiation facilities/establishments regulated by FDA that aim to file the following applications: License to Operate (LTO), Certificate of Compliance (COC), Certificate of Registration (COR), Clearance for Customs Release (CFCR), Radiofrequency Radiation (RFR) Safety Evaluation Report.

III. GUIDELINES

For applications with the CDRRHR-RRD, the following guidelines shall apply. An illustrative guide is annexed as a reference.

1. All payments for applications (i.e. LTO, COC, COR, CFCR, RFR) filed with CDRRHR-RRD shall be assessed through the FDA Payment Portal, http://rrdpayment.fda.gov.ph.

2. Applicants shall provide the details, as indicated in the online forms, to facilitate the processing of applications. These details include, but are not limited to, the following:

a. For LTO, COC, COR Applications

i. Application Type
ii. Validity Date of existing/previous marketing authorization
iii. Details of the Facility/Establishment

1. Name
2. Complete Address
3. Contact Details (e-mail, mobile, landline, fax)

iv. Details of the Machine/s

1. Manufacturer
2. Unit Model
3. Maximum mA
4. Maximum kVp
5. Console Serial No.
6. Tube Serial No.
7. Application/Use

b. For CFCR Applications

i. Application Type
ii. Name of Importer
iii. Radiation Emitting Device to be Imported (maximum of 30 units per application)
iv. Details of the Facility/Establishment

1. Name
2. Complete Address
3. Contact Details (e-mail, mobile, landline, fax)

c. For RFR Safety Evaluation Report Applications

i. Application Type
ii. RFR Facility Owner/Service Provider
iii. Contractor/Subcontractor Name
iv. RFR Transmitter Site
v. Details of the Facility/Establishment

1. Name
2. Complete Address
3. Contact Details (e-mail, mobile, landline, fax)

3. Payments shall be made in accordance to the existing collection policy (i.e. FDA Circular No. 2017-010), and through authorized payment channels only.

4. For Land Bank of the Philippines (LBP) Oncoll Payment Facility transactions, the applicant facility shall follow these simple instructions:

- Print the system generated Order of Payment after successfully completing the online assessment form.
- Proceed to any Land Bank of the Philippines (LBP) branches