



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR
No. 2018-004

03 / 06 / 18

TO : **ALL RADIATION FACILITIES/ESTABLISHMENTS
REGULATED BY THE FOOD AND DRUG
ADMINISTRATION**

SUBJECT : **Guidelines for Payment of Applications with the Radiation
Regulation Division of the Center for Device Regulation,
Radiation Health and Research**

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
 - Present the printed Order of Payment to the LBP and properly fill up the Oncoll Payment Slip.
 - Write down the following in the Oncoll payment slip
 - For Merchant/ Agency Deposit Account Number – refer to Payable to Account Number indicated in the Order of Payment
 - For Merchant/ Agency Name – indicate FOOD AND DRUG ADMINISTRATION

- For reference Number 1 – refer to the System Generated Reference Number which can be seen in the Order of Payment
 - For Reference Number 2 – indicate the applicant facility name
- Present the Order of Payment and the filled up Oncoll payment slip at the LBP teller
- Secure the machine validated LBP Oncoll payment slip as proof of payment

The payment of fee is not a guarantee that the application will be approved. The processing of the application will still be subject to the evaluation of the concerned FDA personnel and its compliance with the pertinent laws, rules and regulations.

5. Once an application has been paid, the applicant facility shall submit the photocopy of the machine validated Oncoll payment slip together with the application documentary requirements to any designated FDA or Department of Health (DOH) receiving offices.

IV. SEPARABILITY CLAUSE

In case any section or provision of this Order or any part thereof, or the application of such section, provision or portion shall be declared invalid, the validity of the remaining provisions of this Order shall not in any way be affected or impaired thereby.

V. REPEALING CLAUSE

Any other order, memorandum, issuances, rule and regulation which is inconsistent with the provisions of this Order is hereby modified or repealed accordingly.

VI. EFFECTIVITY

This Circular shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and upon filing with the UP Law Centre, Office of the National Administrative Register.

NELA CHARADE G. PUNO, RPh
FDA Director General

