



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

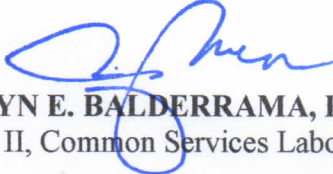


ADVISORY

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DATE : 13 August 2020

TO : All Concerned FDA Marketing Authorization Holders

FROM :   
JOCELYN E. BALDERRAMA, RPh, MBA  
Director II, Common Services Laboratory

SUBJECT : **Online Pre-assessment and acceptance of applications and other authorizations/documents for Lot Release Certification**

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This is in reference to the Memorandum on the pre-assessment and acceptance of applications and other authorizations/ documents for Lot Release Certification (LRC) dated 22 June 2020. Please be guided with the changes in the procedure and submission pertaining to Lot Release Certification as follows:

1. Pre-assessment of Lot Release Certification (LRC) applications will ONLY be accommodated through [cslvbu@fda.gov.ph](mailto:cslvbu@fda.gov.ph) from Mondays to Fridays, 8 a.m. to 3 p.m. All submissions shall contain all the documentary requirements for LRC in pdf format.

**Note:** In lieu of the actual submission of the samples, pictures of the representative samples will be accepted. It shall contain primary and secondary packaging material bearing the applied lot, diluent and sterile needles, if applicable. Post submission of actual samples are required once community quarantine has been lifted.

2. All applications found acceptable during the pre-assessment shall be given 14-digit Document Tracking Number (DTN) for payment and tracking purposes. All online applications received after 3 p.m. will be pre-assessed on the next working day.
3. Clients with accepted online pre-assessed applications shall send an email to [csl@fda.gov.ph](mailto:csl@fda.gov.ph) with the subject: Lot Release Initial Application\_DTN No. (e.g.: Lot Release Initial Application\_DTN20200814124567).

The following documents should be attached in order to process the application, to wit:



- a. Excel copy of the application form
- b. Scanned copy (in pdf format) proof of acceptance
- c. Accomplished Assessment Slip; and
- d. Official Receipt or machine-validated Landbank Oncoll Payment Slip

Subsequently, the CSL – Receiving and Releasing Unit (RRU) shall acknowledge receipt of the email and provides Lot Release Application Number for request with complete attachments.

**Note 1:** Payment can be done through the following modes:

- a. Over the counter payment at FDAC
  - b. Online Collection Payment of Land Bank of the Philippines (using OnColl Payment Slip)
4. Applications for Additional Shipment, Compliance, Amendment and other submissions related to LRC shall be forwarded to [csl@fda.gov.ph](mailto:csl@fda.gov.ph) copy furnished: [cslvbu@fda.gov.ph](mailto:cslvbu@fda.gov.ph) with appropriate subject heading and the previously issued DTN.

**Note 1:** Documentary requirements necessary for Additional Shipment and Amendment shall be incorporated in the online submission in pdf format. Incomplete documents shall not be accommodated.

**Note 2:** Application of additional shipment with different packaging lot (e.g. from Lot No. 01AB to Lot No. 01AC) shall include pictures of representative samples in their submission.

5. Releasing of approved Lot Release Certificate shall be at FDAC Releasing. Request for scanned copies of the document shall be coordinated with AFS – Record Section via [records-releasing@fda.gov.ph](mailto:records-releasing@fda.gov.ph).

The online submission shall take effect on 17 August 2020 until 31 December 2020.

For any inquiries or concerns, please feel free to contact us via email or at telephone number: (632) 8-8571900 loc. 1261.

For your information and guidance.

DTN: 20200813153317