



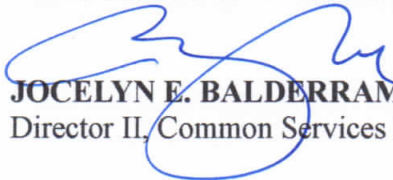
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



MEMORANDUM

DATE : **10 June 2020**

TO : **All Concerned FDA Marketing Authorization Holders**

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

SUBJECT : **Pre-assessment and Acceptance of Applications for Lot Release Certification**

In the consideration of the gaps in the delivery of services due to the current restrictions brought about by the government's response to Covid-19 pandemic, please be advised that an additional mode for the acceptance of applications for lot release pre-assessment has been made available. Applications may be submitted to the Common Services Laboratory – Vaccine and Biological Unit (CSL-VBU) for pre-assessment by email to cslvbv@fda.gov.ph.

Emails shall be separate for each product lot/batch. All requirements (except for the actual representative samples for retention) shall be submitted in PDF format and as separate files. This service shall be available from Mondays to Fridays from 8:00 AM to 5:00 PM. Applications submitted outside of said schedule shall be pre-assessed upon the resume of schedule. An email will be sent to the applicant shortly after the pre-assessment. This may be a clarification (as needed) or acceptance (if complete and satisfactory).

The email of acceptance shall be printed and included in the documents to be submitted in hard copy at the FDA Action Center (FDAC) CSL counter. Acceptance of the application documents and samples for retention shall from Mondays to Fridays from 9:00 AM to 3:00 PM.

However, for applicants who are unable to avail of this online pre-assessment service, they may still submit applications directly at FDAC CSL Counter on Mondays AND Fridays only from 9:00 AM to 3:00 PM, subject to pre-assessment prior to acceptance.

This mode of application shall be available until further notice. For any inquiries or concerns, please do not hesitate to contact us through email or call us at +632 8 8571900 loc. 1261

For your information.

DTN: 20200610161042

