ISSUANCE OF LOT RELEASE CERTIFICATION FOR VACCINES AND BIOLOGICAL PRODUCTS

Issuance of Lot Release Certificate (LRC) for Vaccine and Biological Products to Marketing Authorization Holder (MAH)

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Vaccines and Biologicals Unit FDA Cashier FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Vaccines and Biologicals Marketing Authorization Holder (Importers and Distributors)
Fees to be Paid:	PHP 1,000.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly notarized accomplished Lot Release Application Form with declaration and undertaking	FDA website (www.fda.gov.ph)
2. Self-Assessment Checklist for Lot Release Certification.	FDA website (www.fda.gov.ph)
3. Certificate of Product Registration (CPR) complete with its annexes (Certificate of Variation, if any) and valid at the time of application	Applicant
4. Valid License to Operate (LTO) of the: a. Manufacturer (if applicable) b. Distributor c. Importer	Applicant
5. Certificate of Analysis (CoA) for the Final/ Finished Product (and for the diluent as necessary)	Applicant
6. Three (3) final containers of representative product samples in their final packaging representation in proper storage condition as per approved specification. *(Note: For products with multiple final containers in one (1)*	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
box, only three (3) final containers are required but will still be submitted inside the box)	
7. SOP for Sampling Method from the license holder	Applicant
8. Complete Summary Lot Protocol (SLP)	Applicant
9. Manufacturing Process Flow Diagram	Applicant
10. Batch Numbering System	Applicant
11. For imported products, Lot Release Certificate (or equivalent National Regulatory Authority (NRA) certification) from the country of origin of the product	Applicant
12. One (1) set of final packaging materials as seen on the actual samples (including primary and secondary packaging/labels that of the diluent, and package insert)	Applicant
13. Generic Labelling Exemption (if applicable)	Applicant
14. Pro forma invoice, packing list, shipping invoice or any document indicating the lot number and actual number of doses/units delivered/shipped in the Philippines (for imported products)	Applicant
15. Temperature monitoring data during shipment (Cold Chain Documents)	Applicant
Additional Requirements	
• **For government-procured products (Expanded Program on Immunization (EPI's) and non-EPI's):** • Purchase Order and Notice of Award from the Department of Health	Department of Health
• **For donated vaccines/ biological products:** • Identification of Medical Officer who will be responsible for prompt reporting Adverse Drug Reaction (ADR)/ Adverse Event Following Immunization (AEFI), among others to FDA and/or Report/ Recommendation of the Field Regulatory Operations Office (FROO) on the inspection of the actual shipment	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits application for pre-assessment to cslvbu@fda.gov.ph. All submissions shall contain all the specified documentary requirements for National Lot Release in PDF format. *Note:* If a file to be provided is too large to be an email attachment, link to a cloud storage (e.g., Google Drive, Microsoft OneDrive, etc.) may be allowed, provided that all files have download privileges.	1.1. Pre-assess the application as to the completeness of requirements. • If found to be non-compliant, Applicant will be informed via email indicating the deficiencies and/or discrepancies noted and will be advised to submit necessary documents prior to acceptance. • If found to be compliant, Applicant will be informed via email and will be issued with Document Tracking Number (DTN) and an assessment slip.	None	–	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
2. Proceeds to their preferred payment channel.	2.1. Posting of payment.	PHP 1,000/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
3. Sends documentary requirements via csl@fda.gov.ph with the subject:	3.1. Reviews and checks submitted documentary requirements, and performs the following steps:	None	1 Hour	*Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
National Lot Release Initial Application_DTN(14-digit number) - Filled out Excel copy of the application form; - Scanned copy of proof of acceptance in PDF format; - Accomplished assessment slip; and - Official receipt or machine-validated Landbank ONCOLL payment slip.	• Assigns LRV No. • Fills out the necessary information in the Excel copy of the application form. • Records information to CSL-Receiving and Releasing Unit Database. • Inform CSL-Vaccine and Biological Unit and the Applicant on the receipt of the application. • Forwards the documentary requirements via email to cslvbu@fda.gov.ph.			
4. Submits the representative sample/s and notarized application form at the FDA Central Office, Alabang, Muntinlupa City.	4.1. Checks the application requirements and representative sample/s.	None	2 Hours	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
	4.2. Receives and reviews documentary requirements, and decks the application for evaluation.	None	2 Hours	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	4.3. Evaluates the application and prepare the corresponding worksheet/s. Performs visual examination of samples, updating Section Database, and wrapping and tagging of samples.	None	5 Days	
	4.4. Review of Worksheet and Preparation of Lot Release Certificate or Letter of Denial (as applicable, indicating noted findings as to why safety and quality could not be established).	None	4 Hours	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Vaccine and Biological Unit
	4.5. Reviews and approves Lot Release Certification or Letter of Denial (as applicable).	None	30 Minutes	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
	4.6. Signs the Lot Release Certificate or Letter of Denial (as applicable).	None	10 Minutes	*Director II* CSL
	4.7. Forwards signed Lot Release Certificate or Letter of Denial (as	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	applicable) to FDA Records.			
	4.8. Scans and releases Lot Release Certificate or Letter of Denial (as applicable) to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

NOTES:

1. Online pre-assessment service shall be available from Mondays to Fridays except for holidays and suspension of work, when deemed necessary (e.g., acts of nature), from 8:00 AM to 3:00 PM. Applications submitted beyond 3:00 PM shall be pre-assessed the following working day.
2. Commencement of Day 1 processing is applicable only to applications with submitted Machine Validated Landbank ONCOLL Payment or applications with verified and posted payment by the FDA Cashier.
3. Linkbiz payment verification (3 to 5 days).