APPLICATION FOR VACCINE and BIOLOGICAL PRODUCT LOT RELEASE CERTIFICATION

DTN:	
LABORATORY NUMBER:	
☐ACCEPTED ☐NOT ACCEPTED	
Received by	
Signature	
Date	
PAYMENT DETAILS	
Amount	
OR No.	
Date of Payment (dd/month/yyyy)	
(FOR FDA USE ONLY)	

Date: _____

THE DIRECTOR GENERAL
Food and Drug Administration
Filinvest Corporate City, Alabang
City of Muntinlupa

ATTENTION: COMMON SERVICES LABORATORY

In accordance with Administrative Order No. 47-A series of 2001, we wish to apply for Lot Release certification of our product. We submit herewith the following information and the requirements for lot release processing.

PRODUCT INFORMATION		
FDA Registered International Non-Proprietary Name, Dosage Strength, Dosage Form and Mode of administration:	FDA Registered Brand Name:	
FDA Product Registration Number:	Certificate of Product Registration (CPR No.):	Date of Expiration of CPR (dd/month/yyyy):
Complete Name of Manufacturer:	FDA LTO No. of Manufacturer (if applicable):	Validity of LTO of Manufacturer (dd/month/yyyy):
Complete Address:		

PRODUCT INFORMATION		MANUFACTURING INFORMATION	
Lot/Batch Number (Fill Lot if any):	Date of Manufacture (dd/month/yyyy):	Date Released by Manufacturer (dd/month/yyyy):	
		No. of Final Containers in Lot/Batch:	
Final Packaging Lot:	Expiration Date (dd/month/yyyy) :	Final Packaging as per CPR:	
		Type of Final Container In Lot/Batch:	
Storage Condition as per CPR:	Number of Samples Submitted:	Number of Dose per Final Container:	
Is the subject lot in the Philippines? Yes _____ No. _____	Number of Labels Submitted:	Number of Inserts Submitted:	
If yes, where is it stored/located?	If yes, how many final containers/doses?	If yes, when did it arrived? (dd/month/yyyy)	
DETAILS OF LRC CERTIFICATE FROM THE COUNTRY OF ORIGIN			
Name of NRA:	Batch/Lot Approved:	Date of Issuance as per NRA approval:	Expiration Date of the Product as per NRA:

COMPANY INFORMATION		
Complete Name of Establishment Holding the CPR:	Tel. No.:	
Complete Address:	Fax No.:	
Name of Applicant/Representative:	Position:	e-mail address:
Signature:	Date (dd/month/yyyy):	

DECLARATION

I, the undersigned, hereby declare under oath that:

1. The particulars given in this application are true and all data and information of relevance in relation to the release of this lot have been supplied, as well as, the documents attached herein are authentic or true copies.
2. I agree that the grant of certification shall be automatically revoked by the FDA in the event that there is subsequent findings or misrepresentation in any of the data indicated in the required documents or any of the said documents is subsequently found to be falsified or fraudulently filed; and/or in any case the samples belonging to the same batch/es collected through post monitoring surveillance shall be found not to conform to the product's registered specification or approved labelling.
3. The company that I represent shall automatically cease and desist from further distributing the batch/lot of vaccine and/or biological product subject for revocation upon receipt of notice of cancellation of lot release and pending any administrative proceeding until further notice from the FDA.
4. I or my company undertake to:
    i. Ensure that the product's technical and safety information is made readily available to the FDA anytime when requested, and to keep records of the distribution of the products for product recall or withdrawals purposes.
    ii. Notify FDA as soon as possible by telephone, facsimile transmission, email and in any case as soon possible after first knowledge of any Adverse Event Following Immunization (AEFI) or any serious adverse event if the cause, whether proximate or otherwise, of such adverse events is the use of the above product.
    iii. Respond to and cooperate fully with the FDA officers with regard to any subsequent post marketing activity or any investigation initiated by the FDA.
5. I hereby acknowledge that failure to submit the complete requirements and give the correct information shall be grounds for outright denial of this application and forfeiture of all payments.

Pharmacist (as per LTO): _____

PRC License Number: _____

Signature: _____

Date: _____