VBC Reference: _____

APPLICATION FOR VACCINE REGISTRATION

This form may take you 10 minutes to fill in. You will need the following information to complete the form:

- Business/Company Registration No (Please attach RCB profile)
- Information on the product and manufacturer, outline of production, quality control tests and developmental studies etc. as listed in Section II and Annex I.

Please complete the Application Form and submit it together with the registration dossier to AVS_Vaccine_Registration@nparks.gov.sg or the following address:

Veterinary Biologics Committee (VBC)
Animal and Plant Health Centre
6 Perahu Road, Singapore 718827

The registration fee is $210.00. A tax invoice will be sent to you once application is received.

SECTION I : INFORMATION OF APPLICANT/COMPANY

Name of applicant:	NRIC/Passport No.:
Name of Company:	Business/Company Reg. No.:
Address of Company:	S( )
Telephone No.	Facsimile No.:
Email:	

SECTION II: INFORMATION FOR VACCINE REGISTRATION

State "NA" if information is Not Applicable to this product.
State "Not Available" if such information is not available for this product.
All fields have to be completed.

NAME OF PRODUCT: _____

ACTIVE INGREDIENT(S): _____

_____**(LIVE / KILLED / LIVE MODIFIED / OTHER)**

COUNTRY OF ORIGIN: _____

MANUFACTURER: _____

MANUFACTURING SITE: _____

(Please complete the details in Annex I)

SECTION III: DECLARATION

I hereby apply for the registration of the aforementioned vaccine product. I certify that the information given and all supporting documents attached in respect of this vaccine product are true, correct and complete. I understand that any false, inaccurate or incomplete information supplied will result in the rejection of my application or cancellation of a registration.

Signature of applicant & company stamp	Position in company	Date

Annex I

Part A: ADMINISTRATIVE DOCUMENTATION

Section	Documents		Technical Dossier Vol /Annex & Page No.(s)	For official use only
1.	**Comprehensive Table of Contents**			
2.	**Manufacturing Company information**			
	2.1	Name and address of manufacturer		
	2.2	Valid establishment licence For new establishments: information of the production and quality control facilities as well as personnel		
	2.3	Product licence		
	2.4	GMP certification / proof of GMP compliance for product		
	2.5	Certificate of Free Sale		
	2.6	Other relevant documents		
3.	**Product Information**			
	3.1	Name & description of product		
	3.2	Label Claim / Indications		
	3.3	Packaging, shelf-life & storage conditions		
	3.4	Product formula – full composition of active substances and excipients that are present in the final dosage form		
	3.5	A list of all ingredients of animal origin used in the production of the biological product, including the country of origin		
	3.6	Freedom from BSE certification from relevant authority, certifying that ingredients of bovine origin are obtained from countries where there are no cases of BSE, or equivalent		
	3.7	Dosage form		
	3.8	Route(s) of administration – include target species and all routes of administration, with-holding period		
4.	**Registration Status in other countries**			
	4.1	Relevant supporting certificates, documents		

PART B: SEED INFORMATION

Section	Documents		Technical Dossier Vol /Annex & Page No.(s)	For official use only
5.	**History of Master Seed**			
	5.1	Full name of strain or serotype		
	5.2	History, origin, source and characteristics of master seed and working seed		

PART C: MANUFACTURING DETAILS

Section	Documents		Technical Dossier Vol /Annex & Page No.(s)	For official use only
6.	**Product Information**			
	6.1	Description of manufacturing process and process controls		
	6.2	Attenuation and / or inactivation process (for inactivated vaccines)		
	6.3	Control of materials		
	6.4	Controls of critical steps and intermediates		
	6.5	Process validation and/or evaluation		
7.	**Description of container and outer package**			
	7.1	Description of the type of container, stopper, cupping, etc, having direct contact with the vaccine		
	7.2	The requirements and test methods for airtight containers, possible leakages and any possible drug and container interaction		
	7.3	Description of the outer package of the vaccine container (if applicable), type and quality of outer package material		
8.	**Product label**			
	8.1	Container label and outer packaging label		
	8.2	Product insert		

PART D: QUALITY

Section	Documents		Technical Dossier Vol /Annex & Page No.(s)	For official use only
9.	**Product Information**			
	9.1	Method of propagation and storage of MS & WS		
	9.2	Seed lot system : number of passages from MS		
	9.3	Quality control tests of MS & WS		
	9.4	Identity test for MS		
	9.5	Immunogenicity of MS / determination of minimum protective dose		
	9.6	Validation of MS immunogenicity every 3 years		
	9.7	Efficacy in target species		
10.	**Quality control of substrate and raw materials**			
	10.1	Specifications of production substrate (eg SPF eggs, culture media). For SPF eggs, standards to which SPF chickens are tested.		
	10.2	Specifications and quality control of media and other chemicals used		
11.	**Control of Finished Product**			
	11.1	Physical properties of product, appearance, vacuum, pH, etc		
	11.2	Moisture content		
	11.3	Test for residual preservative or inactivating agent, eg: phenol, thiomersal, formaldehyde (inactivated vaccines)		
	11.4	Identity test		
	11.5	Sterility test for freedom of contaminating bacteria, fungus, Mycoplasma and Salmonella (where applicable)		
	11.6	Purity from extraneous viruses		
	11.7	Inactivation test (inactivated vaccines)		

	11.8	Safety test (safety in laboratory animals should be correlated with safety in target species)		
	11.9	Potency test (In-vivo potency tests should be correlated with efficacy in target species)		
	11.10	Measurement of virus, bacterial or specific antigen content		
	11.11	Quality control reports of 3 recent batches		
12.	**Stability**			
	12.1	Method for conducting stability testing, properties used for determining stability		
	12.2	Minimum dose or titre at release & expiry		
	12.3	Stability data of at least three (3) batches of finished product		

PART D: QUALITY

Section	Documents		Technical Dossier Vol /Annex & Page No.(s)	For official use only
13.	**Tabular listing of All Clinical Studies**			
14.	**Reports of Efficacy and Safety Studies** - including Purpose of experiment; materials and methods, location, responsible person / veterinarian, dates of trial, results of trial, discussion and conclusion.			
	14.1	Safety of an overdose in target animals of minimum age, including post-vaccinal responses (toxicity, allergy, postvaccination reaction and side effects)		
	14.2	Efficacy studies		
	14.3	Determination of minimum protective dose, immunogenicity test		
	14.4	Reversion to or enhancement of virulence by animal passage (live vaccines)		
	14.5	Transmissibility studies (live vaccines)		
	14.6	Effect of maternal antibody		
	14.7	Immunological response, duration of immunity		
	14.8	Interference studies – effect of other immunisations		
	14.9	Where serological response is used as a measure of potency, correlation of serological values to immunogenicity in target species		
	14.10	Where antigenic or virus content is used as a measurement of potency, correlation to immunogenicity in the target species		
	14.11	Role of cell-mediated immunity, if any (especially where antibody response is used to measure vaccine efficacy)		
	14.12	Endotoxicity & safety studies of inactivated vaccines for non-avian species		
	14.13	Field safety & efficacy trials, indicating locations of trials, number of animals, responsible person / veterinarian		
	14.14	Other supporting documents & studies		

PART F: PHARMACOVIGILLANCE

Please list the usage of the vaccine in registered countries and pharmacovigilance reports. An abstract in English must accompany all non-English publications.

PART G: REFERENCES

Please list attached references in a separate document or in your table of contents. An abstract in English must accompany all non-English publications.