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FOOD AND DRUGS AUTHORITY

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS

APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS (To be submitted in duplicate electronic copies)

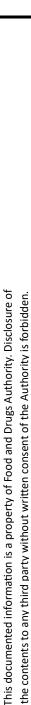
Cover letter addressed to:

THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS-ACCRA
GHANA.

Note: Samples and electronic documents should be forwarded to the FDA through the local agent; customs duty and clearance are to be effected by the applicant in all instances.

SUBMISSION SHOULD ALWAYS BE DONE BY A COMPETENT TECHNICAL OFFICER

1. PRODUCT DETAILS (MUST BE COMPLET	ED)
Full Name of Product (proprietary name):	
Human: □ Veterinary (if vet	erinary, state target species): □
Please tick where applicable	
International Non-Proprietary Name (INN):	
Is this biological product registered in other cou	intries?
If yes, list countries and registration numbers:	
European Union (EU) status (please provide dat	e and number:
Pharmaceutical form:	
Route of Administration	
Concentration/Strength:	





Appearance/Colour:

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DOC. TYPE: FORM

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Category of distribution:		
Country(s) of origin of Finished Biological Product:		
Applicant /Marketing authorization holder:		
Applicant/ Marketing authorization number & date (country of origin)		
2. APPLICANT/ MARKETING AUTHORIZATION HOLDER CONTACT INFORMATION (MUST BE COMPLETED)		
Full name of Applicant/Marketing Authorization Holder (<i>must be a company</i>):		
Manufacturing company registration certificate number (including accessory companies):		
Name of contact person(s):		
Title and / or designation:		
Street or physical address:		
Postal address:		
E-mail address:		
Telephone number:		
3. LOCAL AGENT CONTACT INFORMATION (MUST BE COMPLETED)		
Note: Only a body incorporated in Ghana can be appointed as a local agent for this application		
Full name of local agent (must be a registered company):		
Registrar general's registration number:		
Name of Contact person (s):		
Title and /or designation:		



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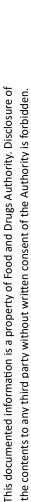
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Postal address:	_		
Street or physical add	ress:		
E-mail address:			
Telephone number:			
Full name of Superinte	endent Pharmacist:		
Registration number o	f Superintendent Pharm	nacist:	
	(MUST BE COMPLET	,	
Two (2) soft copies (one CD-ROM and a DUPLICATE CD-ROM) of completed application forms and the dossier in the Common Technical Document (CTD) format must be submitted as stated in the guideline on the registration of a biological product.			
5. DISTINCT PRES	CRIBED USE (INDICA	TION) (MUST BE COM	PLETED)
List all proposed distinct uses (for veterinary, state target species and situation)			
6. TABLE OF FORMULATION DETAILS (MUST BE COMPLETED)			
(A) Name of Biological active constituent	Concentration/ Quantity	Specification	Purpose in formulation
(B) Excipients	Concentration/ Quantity	Specification	Purpose in formulation





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Does the product cont	ain ingredients with a ri	sk of transmitting agent	s of animal
spongiform encephalo	pathy?		
Vaa 🗆		No □	
Yes □		No □	
Does the product cont from a GMO?	ain a genetically modifi	ed organism (GMO) or	any product derived
Yes □		No □	
Does the finished form	nulation contain any ing	redient of human origin	?
Yes □		No 🗆	
		turing and techniques, and techniques, and the ingre	
certificates to demons	trate the virus/patrioger	i-free status of the ingre	culetit.
7. MANUFACTURERS' DETAILS (MUST BE COMPLETED)			
The manufacturer must be licensed to manufacture the product for which this registration			
application applies. In	clude the name and stre	eet address of all faciliti	es involved in any
		abelling, contractors and	d analytical
laboratories where applicable.			
Company name	Company's	Street/physical	Extent/Stage of
. ,	registration	address of	manufacture
	number	manufacturing site	(Attach flow
			(Attach flow diagram)
			ulagraili)
1.			
2.			
3.			
4.			

Provide details of responsible person performing 'Release for Supply':



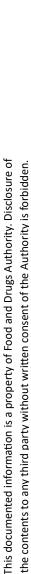
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Name of responsible person:			
Position:			
Company name:			
Street address:			
E-mail:			
Telephone number:			
8. EVIDENCE OF GOOD MA	ANUFACTURIN	IG PRACTICE	(MUST BE COMPLETED)
Indicate Good Manufacturing I	Practice (GMP)	certificate and	submit valid copies.
Manufacturer(s):	Evidence of GMP:		GMP:
1.		1.	
2.		2.	
3.		3.	
4.		4.	
9. MANUFACTURER(S) OF ACTIVE CONSTITUENTS (MUST BE COMPLETED)			
	Active constit	uent	Active constituent (if applicable)
Name and site address of manufacturer			
Active constituent			
Reference (EP, BP, USP, IP, other specification)			
Source/history of culturing and extraction			

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Identity (strain, genus, species and serotype/biotype)			
Unique identifier/descriptor (gene/phage type, molecular weight extract etc.)			
Master seed code and passage level			
Working seed code and passage level			
Note: If the product contains more than two active constituents, please attach a separate table.			
10. CONTAINER AND PACK SIZE DETAILS (MUST BE COMPLETED)			
Proposed pack size(s)	Brief description of the packaging material, including that which is in direct contact with the product (i.e., primary and secondary packaging).	Method of label attachment	
Provide details of product presentation (e.g., single glass bottle inside individual cardboard carton with enclosed leaflet).			
11. STORAGE STABILITY	DETAILS (MUST BE COMPL	ETED)	
The proposed shelf life from the manufacture:	ne date of		
· ·	ne date of		



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Submit a comprehensive stability study protocol, data and report on three (3) consecutive batches to support the storage stability of the product. For biological products in multiple dose containers: Submit an in-use stability study to support the in-use shelf life of the product. Submit a detailed storage temperature profile of the product (i.e., transportation and excursions). LABEL DETAILS 12. Product Information Leaflet submitted Yes No 🗆 Summary of Product Characteristics (SmPC) submitted Yes 🗆 No 🗆 13. DECLARATION (MUST BE COMPLETED) All correspondence about this application shall be addressed to the Applicant/ Marketing Authorization Holder unless otherwise specified. I declare that the above information provided with this application is complete and correct. Signature of Applicant/ Marketing Authorization Holder: Date: ___/___/ Official stamp: False declaration may lead to prosecution.

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