

 FOOD AND DRUGS AUTHORITY <small>Your Well-being, Our Priority.</small>	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/VBP/FOR – 23	
		Page 1 of 7	Ver. No.: 02
		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 COMPLETED)	
Full Name of Product (proprietary name):	
Human: <input type="checkbox"/>	Veterinary (if veterinary, state target species): <input type="checkbox"/>
Please tick where applicable	
International Non-Proprietary Name (INN):	
Is this biological product registered in other countries?	
If yes, list countries and registration numbers:	
European Union (EU) status (please provide date and number:	
Pharmaceutical form:	
Route of Administration	
Concentration/Strength:	

 Your Well-being, Our Priority.	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/VBP/FOR – 23	
		Page 2 of 7	Ver. No.: 02
		Effective Date: 05/09/2025	
TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS			

Appearance/Colour:
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 (<i>including accessory companies</i>):
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)
<i>Note: Only a body incorporated in Ghana can be appointed as a local agent for this application</i>
Full name of local agent (must be a registered company):
Registrar general's registration number:
Name of Contact person (s):
Title and /or designation:

 <div> <div>FOOD AND DRUGS AUTHORITY</div> <div>GHANA</div> <div>Your Well-being, Our Priority.</div> </div>	<div>FOOD AND DRUGS AUTHORITY</div>	DOC. TYPE: FORM	
		DOC NO.: FDA/VBP/FOR – 23	
		Page 3 of 7	Ver. No.: 02
		Effective Date: 05/09/2025	
<div>TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS</div>			

Postal address:
Street or physical address:
E-mail address:
Telephone number:
Full name of Superintendent Pharmacist:
Registration number of Superintendent Pharmacist:
4. PRODUCT DATA (MUST BE COMPLETED)
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 PRESCRIBED USE (INDICATION) (MUST BE COMPLETED)			
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

 <div> <div>FOOD AND DRUGS AUTHORITY</div> <div>GHANA</div> <div>Your Well-being, Our Priority.</div> </div>	<div>FOOD AND DRUGS AUTHORITY</div>	DOC. TYPE: FORM	
		DOC NO.: FDA/VBP/FOR – 23	
		Page 4 of 7	Ver. No.: 02
		Effective Date: 05/09/2025	
<div>TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS</div>			

<div>Does the product contain ingredients with a risk of transmitting agents of animal spongiform encephalopathy?</div> <div> <div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div> </div>			
<div>Does the product contain a genetically modified organism (GMO) or any product derived from a GMO?</div> <div> <div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div> </div>			
<div>Does the finished formulation contain any ingredient of human origin?</div> <div> <div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div> </div> <div>If yes: Provide detailed information on the culturing and techniques, as well as all certificates to demonstrate the virus/pathogen-free status of the ingredient:</div>			
<div>7. MANUFACTURERS' DETAILS (MUST BE COMPLETED)</div>			
<div>The manufacturer must be licensed to manufacture the product for which this registration application applies. Include the name and street address of all facilities involved in any step of manufacture, including packaging & labelling, contractors and analytical laboratories where applicable.</div>			
Company name	Company's registration number	Street/physical address of manufacturing site	Extent/Stage of manufacture (Attach flow diagram)
1.			
2.			
3.			
4.			
<div>Provide details of responsible person performing 'Release for Supply':</div>			

 FOOD AND DRUGS AUTHORITY <small>Your Well-being, Our Priority.</small>	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/VBP/FOR – 23	
		Page 5 of 7	Ver. No.: 02
		Effective Date: 05/09/2025	
TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS			

Name of responsible person:		
Position:		
Company name:		
Street address:		
E-mail:		
Telephone number:		
8. EVIDENCE OF GOOD MANUFACTURING PRACTICE (MUST BE COMPLETED)		
Indicate Good Manufacturing Practice (GMP) certificate and submit valid copies.		
Manufacturer(s): 1. 2. 3. 4.	Evidence of GMP: 1. 2. 3. 4.	
9. MANUFACTURER(S) OF ACTIVE CONSTITUENTS (MUST BE COMPLETED)		
	Active constituent	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		

 <div> <div>FOOD AND DRUGS AUTHORITY</div> <div>GHANA</div> <div>Your Well-being, Our Priority.</div> </div>	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/VBP/FOR – 23	
		Page 6 of 7	Ver. No.: 02
		Effective Date: 05/09/2025	
TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS			

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 COMPLETED)		
The proposed shelf life from the date of manufacture:		
Proposed in-use shelf life:		
Proposed storage conditions: (e.g., between 2°C and 8°C. Refrigerate. Do not freeze)		



DOC. TYPE: FORM

Page 7 of 7

Ver. No.: 02

TITLE: APPLICATION FORM FOR INNOVATOR BIOLOGICAL PRODUCTS

For biological products in multiple dose containers:

Submit a detailed storage temperature profile of the product (i.e., transportation and excursions).

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.