



Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR BIOSIMILAR PRODUCTS

# APPLICATION FORM FOR BIOSIMILAR 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 Biosimilar Produc	t (proprietary name):	
Human: □	Veterinary (if veterinary, state target species): □	
Please tick where applicable		
International Non-Proprietary N	lame (INN):	
Is this biosimilar registered in o	ther countries?	
Yes □	No 🗆	
If yes, list countries and registra	ation numbers:	
European Union (EU) status (please provide date and number if applicable):		
Pharmaceutical form:		
Route of Administration		
Concentration/Strength:		
Appearance/Colour:		



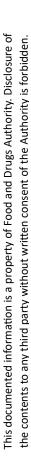


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Category of distribution:
Proposed distribution network:
Country of origin of Finished Biosimilar Product:
Applicant / Marketing authorization holder name:
Applicant / Marketing authorization number & date (country of origin):
2. REFERENCE PRODUCT DETAILS (MUST BE COMPLETED)
Proprietary name:
International non-proprietary name (INN):
Is the reference product registered in other country?
Yes □ No □
If yes, list countries and registration numbers:
3. APPLICANT/MARKETING AUTHORIZATION HOLDER'S CONTACT DETAILS (MUST BE COMPLETED)
Full name of Applicant/ Marketing Authorization Holder (must be a company):
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:
4. LOCAL AGENT CONTACT DETAILS (MUST BE COMPLETED)





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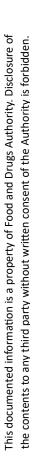
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Note: Only a body incorporated in Ghana can be appointed as a local agent for this application
Full name of local agent (must be a registered company):
Registrar General's registration number:
Name of contact person (s):
Title and /or designation:
Postal address:
Street or physical address:
E-mail:
Telephone number:
Full name of Superintendent Pharmacist:
Registration number of Superintendent Pharmacist:
5. PRODUCT DATA
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.
6. DISTINCT PRESCRIBED USES (INDICATION(S))
List all proposed <b>distinct</b> uses (for veterinary, state target species and situation)
7. TABLE OF FORMULATION DETAILS





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(a) Name of Biological active constituent	Concentration/ Quantity	Specification	Purpose in formulation
(b) Excipients	Concentration/ Quantity	Specification	Purpose in formulation
Does the product contain ingredients with a risk of transmitting agents of animal spongiform encephalopathy? Yes □ No □			
Does the product contain a genetically modified organism (GMO) or any product derived from a GMO? Yes □ No □			
Does the application submission contain information on the source(s) of raw materials (Biological and non-biological)?  Yes □ No □			
Does the finished formulation contain any ingredient of human origin?  Yes □ No □			
If yes, provide detailed information on the culturing and extraction techniques, as well as all certifications to demonstrate the virus/pathogen-free status of the ingredient.			
8. COMPARABIL	ITY DATA		
soft copy -DUPLIC		rmat saved on a C	information shall be provided in D). (Refer to page 26 of GHFDA
9. MANUFACTU	RERS' DETAILS (I	MUST BE COMPL	ETED)





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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.

laboratories where ap		aboming, contractors are	a analytical
Company name	Company's registration number	Street/physical address of manufacturing site	Extent/Stage of manufacture (Attach flow diagram)
1.			-
2.			
3.			
4.			
Provide details of responsible person performing 'Release for Supply':			
Name of responsible	person:		
Position:			
Company name:			
10. EVIDENCE OF G	OOD MANUFACTURII	NG PRACTICE (MUST	BE COMPLETED)
Indicate Good Manufa	acturing Practice (GMP	) certificate and submit	valid copies.
Manufacturer(s):		Evidence of GMP:	
1.		1.	
2.		2.	
3.		3.	
11 MANUFACTURE	R(S) OF ACTIVE CONS	STITUENTS (MUST RE	COMPLETED)

# 11. MANUFACTURER(S) OF ACTIVE CONSTITUENTS (MUST BE COMPLETED)





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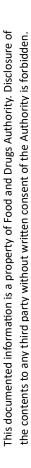
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	Active constituent	Active constituent (if applicable)
Name and site address of manufacturer		
Active constituent		
Reference (EP, BP, USP, IP, other specification)		
Source/history of culturing and extraction		
Identity (strain, genus, species, and 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.

# 12. 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





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Provide details of product pre cardboard carton with enclose	sentation (e.g., single glass bo ed leaflet).	ttle inside individual
13. STORAGE STABILITY D	ETAILS (MUST BE COMPLET	ΓED)
The proposed shelf life from t	he date of manufacture	
Proposed in-use shelf life		
Proposed storage conditions: Refrigerate. Do not freeze)	(e.g., between 2°C and 8°C.	
Submit a comprehensive stab batches to support the storage	ility study protocol, data and re e stability of the product.	eport on three (3) consecutive
For biological products in n	nultiple dose containers:	
Submit an in-use stability stud	ly to support the in-use shelf lif	fe of the product.
Submit a detailed storage to and excursions).	emperature profile of the pro	duct (i.e. transportation
14. LABEL DETAILS		
Product Information Leaflet su	ubmitted	
Yes □	No 🗆	
Summary of Product Characte	eristics (SmPC) submitted	
Yes □	No □	
15. DECLARATION (MUST E	BE COMPLETED)	





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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.