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 Product (proprietary name):
Human: ☐ Veterinary (if veterinary, state target species): ☐ **Please tick where applicable**
International Non-Proprietary Name (INN):
Is this biosimilar registered in other countries? Yes ☐ No ☐
If yes, list countries and registration numbers:
European Union (EU) status (please provide date and number if applicable):
Pharmaceutical form:
Route of Administration
Concentration/Strength:
Appearance/Colour:

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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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 **distinct** uses (for veterinary, state target species and situation)
7. TABLE OF FORMULATION DETAILS

(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. COMPARABILITY DATA

Data must be accompanied by a table of contents, and information shall be provided in soft copy -DUPLICATE (electronic format saved on a CD). (Refer to page 26 of GHFDA guidelines for registration of Biosimilars.)

9. MANUFACTURERS' DETAILS (MUST BE COMPLETED)

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.

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 GOOD MANUFACTURING PRACTICE (MUST BE COMPLETED)

Indicate Good Manufacturing Practice (GMP) certificate and submit valid copies.

Manufacturer(s):	**Evidence of GMP:**
1.	1.
2.	2.
3.	3.

11. 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		
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**

Provide details of product presentation (e.g., single glass bottle inside individual cardboard carton with enclosed leaflet).		
13. 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)		
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).		
14. LABEL DETAILS		
Product Information Leaflet submitted Yes ☐ No ☐		
Summary of Product Characteristics (SmPC) submitted Yes ☐ No ☐		
15. DECLARATION (MUST 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.