



 DOC. TYPE: FORM

 DOC NO.: FDA/VBP/FOR – 26

 Page 1 of 6
 Ver. No.: 02

Effective Date: 05/09/2025

TITLE: APPLICATION RENEWAL FORM FOR BIOSIMILAR PRODUCTS

APPLICATION RENEWAL FORM FOR BIOSIMILAR PRODUCTS (To be submitted in duplicate electronic copy)

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 Authority through the local agent.

SUBMISSION SHOULD ALWAYS BE DONE BY A COMPETENT TECHNICAL OFFICER

1. PRODUCT DETAILS (MUST BE COMPLETED)			
Full Name of Biosimilar product	t (proprietary name):		
Current GHFDA Registration nu	umber:		
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 (pl	lease provide date and number if applicable):		
Pharmaceutical form:			
Route of Administration:			
Concentration/Strength:			
Formulation type:			



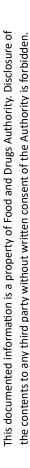


DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 26

Effective Date: 05/09/

Appearance/Colour:
Category of distribution:
Country of origin of Finished Product:
Applicant/Marketing authorization holder:
Applicant/Marketing Authorization number & date (country of origin):
2. REFERENCE PRODUCT (MUST BE COMPLETED)
Proprietary name:
International non-proprietary name (INN):
Is the reference product registered in other countries?
If yes, list countries and registration numbers:
3. APPLICANT /MARKETING AUTHORIZATION HOLDER CONTACT INFORMATION (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:

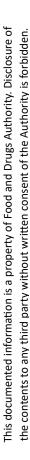




DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 26

4. 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:
Title and /or designation:
Postal address:
Street or physical address:
E-mail address:
Telephone number:
Full name of Superintendent Pharmacist:
Registration number of Superintendent Pharmacist:
5. NAME AND CONTACT DETAILS OF THE QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV) RESPONSIBLE FOR THE FINISHED PRODUCT IN GHANA
Name:
Certificate Number:
Address:
Telephone:
E-Mail:
Signature:
6. PRODUCT DATA





Effective Date: 05/09/2025

TITLE: APPLICATION RENEWAL FORM FOR BIOSIMILAR PRODUCTS

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.

Data may include, but not limited to the following:

- Certificate of analysis of the finished biosimilar
- Certificate of Pharmaceutical Product (CoPP) issued by the statutory national drug regulatory authority, in accordance with the World Health Organization (WHO) Certification Scheme for Pharmaceutical Products Moving in International Commerce
- Long-term/Real-time and real condition stability studies for three (3) production batches (protocol and report)
- Evidence of Good Manufacturing Practice (GMP)

7. REFERENCE PRODUCT USED FOR COMPARABILITY STUDY

State the rationale fo	or the choice of referen	ce product:	
Reference product name	Registration status in Ghana (please indicate as registered or not registered)	Specification	Distinct Prescribed Uses
a DIOTINAT DDEO	DIDED HOLO		

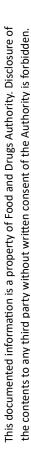
8. DISTINCT PRESCRIBED USES

List all proposed distinct uses (for veterinary, state target species and situation)

9. MANUFACTURER(S) 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)
			,





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR – 26

Effective Date: 05/09/2025

Page **5** of **6**

Ver. No.: 02

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 pre cardboard carton with enclos	, ,	glass b	ottle inside individual	
11. STORAGE STABILITY I	DETAILS (MUST BE C	OMPLI	ETED)	
The proposed shelf life from manufacture:	the date of			
Proposed in-use shelf life:				
Proposed storage conditions between 2°C and 8°C. Refrig freeze)				
Submit a comprehensive state consecutive batches to supp				
For biological products in	multiple dose contair	ers:		
Submit an in-use stability stu	dy to support the in-us	e shelf	life of the product.	
Submit a detailed storage t and excursions).	emperature profile o	f the pr	oduct (i.e., transportation	
12. LABEL DETAILS				
Product information Leaflet S	Submitted:			
Yes □	No□			
Submit summary of product of	· · · · · · · · · · · · · · · · · · ·):		
Yes 🗆	No□			
13. DECLARATION (MUST	BE COMPLETED)			
All correspondence about thi otherwise specified	s application shall be a	ddress	ed to the Applicant unless	



DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 26

I declare that the above information provided with this application is complete and correct.
Signature of Applicant
Date://
Official stamp:
False declaration may lead to prosecution.