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 (proprietary name):
Current GHFDA Registration number:
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:
Formulation type:

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:

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

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 for the choice of reference product:

Reference product name	Registration status in Ghana (please indicate as registered or not registered)	Specification	Distinct Prescribed Uses

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)

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)	
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).	

12. LABEL DETAILS
Product information Leaflet Submitted: Yes ☐ No☐
Submit summary of product characteristics (SmPC): Yes ☐ No☐

13. DECLARATION (MUST BE COMPLETED)
All correspondence about this application shall be addressed to the Applicant unless otherwise specified

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.