Registration Renewal Application 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; 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)
EXISTING FDA REGISTRATION NUMBER: Full Name of Product (proprietary name): Human or Veterinary (if veterinary, state target species):
International Non-Proprietary Name (INN): Is this biosimilar registered in other countries? If yes, list countries and registration numbers: WHO prequalification status (*please provide PQ date*):
Pharmacological classification: Pharmaceutical form: Formulation type: Mode of usage: Concentration/Strength: Formulation type: Appearance/Colour: Proposed use: Active constituent(s):
Category of distribution: Proposed distribution network:
Country of origin: Marketing authorization holder: Marketing authorization number & date (country of origin):

REFERENCE PRODUCT
Proprietary name: International Non- Proprietary name (INN): Is the reference product registered in other countries? If yes, list countries and registration numbers:
FOR OFFICIAL USE ONLY Application tracking number: Registration number: First renewal: Second renewal:
2. APPLICANT CONTACT INFORMATION (MUST BE COMPLETED)
Full name of applicant *(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 (applicant):
Postal address (applicant):
E-mail (applicant): Telephone number(applicant): Fax number (applicant):
3. DECLARATION (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(s): Title and /or designation:
Postal address (local agent):
Street or physical address (local agent):
E-mail (local agent): Telephone number (local agent): Fax number (local agent):
Full name of Superintendent Pharmacist: Registration number of Superintendent Pharmacist:
Correspondence about this application is to be addressed to: Applicant or local agent
I declare that the information provided with this application is complete and correct. Signature (MUST be in ink): _____ Date: _____/_____/_____ Official stamp:

False declaration may lead to prosecution.

4. PRODUCT DATA

Data must be accompanied by a table of content, information should be provided in soft copy –DUPLICATE (an electronic format saved on a CD).

Data may include, but not limited to the following:

- Supporting documentation for any variations since the biosimilar was last registered
- 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)
- Method of analysis (Protocol and Report)
- Analytical Method Validation (Protocol and Report)
- Evidence of Good Manufacturing Practice (**GMP**)
- Batch release documents
- Reference Standard/ Product
- Certificate of Analysis of the Reference Standard/Reference Product
- Risk management plan and pharmacovigilance/data on post market surveillance (*refer to www.fdaghana.gov.gh*)

5. 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**

6. VARIATION(S) MADE TO PACKAGING/PRESENTATION/FORMULATION

Please list all variations made to the primary and/ or secondary packaging/presentation/formulation since initial registration

7. LIST OF ALL CHANGE(S) IN THE CONDITIONS OF USE, LABELLING OR REGISTRATION CONDITIONS FOR THE BIOSIMILAR PRODUCTS

8. COMPARABILITY DATA

Data must be accompanied by a table of contents, information shall be provided in soft copy-DUPLICATE (electronic format saved on a CD). (Refer to page 29 of GHFDA guidelines for registration of Biosimil rs.)

I declare that the provided information is complete and correct.

Signature (MUST be in ink): _____ Date:

False declaration may lead to prosecution.

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 & labeling, 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.			

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. APPLICANT'S CHECKLIST (MUST BE COMPLETED)
Tick the appropriate boxes to verify that required documentation is attached: ☐ Application Overview completed including outline of exact purpose of application (and all relevant attachments) ☐ Appropriate fee ☐ Application form signed in ink and completed all relevant sections

Attachments

Attachments (where applicable) should be indicated in the table of attachments and attached to this Application Form and Overview.

Table of attachments

Attachment	**Attached?**
Product label in appropriate format	
Product Data	
Comparability Data	
GMP certificates/documentation	
GHFDA import permit	
Evidence of purchase of reference product (if applicable)	
Other (specify)	

Note: The entire application should be submitted with a table of contents. The total number of pages in the application, and total number of pages of attachments and appendices should be clearly stated.