Registration 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 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: 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:

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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 shall be provided in soft copy-DUPLICATE (An electronic format saved on a CD).

5. REFERENCE PRODUCT

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. CLINICAL PARTICULARS (DISTINCT PRESCRIBED USES) OF THE BIOSIMILAR

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

7. FORMULATION DETAILS (MUST BE COMPLETED)

Provide the full details below (every constituent must be listed).

Provide the full formulation details of the product. For details on required information, refer to Manufacturing process considerations (section 2.2.2) in the GHFDA Guideline for registration of Biosimilars.

Formulation details submitted on this page can only be disclosed to: (select appropriate–more than one if applicable)

Applicant □ Approved Person □

Manufacturer □ Other Details…….

Note: Unless indicated on this form or separately in writing, formulation details will not be disclosed to any person other than the provider of the information.

TABLE OF FORMULATION DETAILS

(a) Name of Biological active constituent	Minimum release titre	Maximum release titre	End of shelf life titre	Purpose in formulation

(b) Name of Biological active constituent	Concentration/ Quantity	Specification	Purpose in formulation

(c) Name of non-biological active constituent name (if applicable)	Concentration/ Quantity	Specification	Purpose in formulation
(d) Other constituents	Concentration/ Quantity	Specification	Purpose in formulation

Specific gravity (SG) (liquids only):

Formulation type (eg solution, suspension, lyophilized):

Does the product contain ingredients with a risk of transmitting agents of animal spongiform encephalopathy?

Does the product contain a genetically-modified organism (GMO) or any product derived from a GMO?

For imported ingredients of biological origin, copies of relevant GHFDA import Permit must be attached.

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:
(Refer to Manufacturing process considerations (section 2.2.2))

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 29 of GHFDA guidelines for registration of Biosimilars.)

I declare that the provided information is complete and correct.

Signature (MUST be in ink): _____ Date:

False declaration may lead to prosecution.

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.			

10. EVIDENCE OF GOOD MANUFACTURING PRACTICE (MUST BE COMPLETED)

The name and address of the manufacturers shown on the evidence of GMP must correspond with the manufactures detailed under section 8. Indicate the type of evidence provided and submit copies of valid certificates.

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

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

	1st active constituent	**2nd 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

Pack sizes (in content volume; e.g. mL):

Submit four (4) copies of the product label in the appropriate format in accordance with requirements.

15. 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

Application Overview

The application overview below should not exceed 20 pages.

1.1 Introductory Information

(a) Completed application form

[The completed application form is all that is required for section 1.1 (a)]

(b) Executive summary

[Describe the purpose of the application and your reasons for submitting the application. Provide justification for the application]

[Briefly summarize the issues associated with the application]

(c) Biological properties of the product

[Type of immune response and correlation with protection]

(d) Reference product

[Enter the name and product number of the reference product]

(e) Registration status in other countries for this and related formulations

[Provide details of any known current or previous applications or approvals of the biosimilar in other countries]

(f) Has an application been submitted previously for this product?

No…… If Yes, Indicate whether the data presented with this application contradicts or changes the conclusions made from data provided previously.

1.2 Manufacturing process considerations

[Declare whether a separate section 2.2.2 has been provided, if not, justify why it should not be required]

[Briefly (in one paragraph) summarize any stability studies that have been submitted in section 2.2.7]

[Insert the product's batch release and expiry specifications here]

1.3 Toxicology

[Declare whether toxicology studies have been provided. If not, justify why it should not be required]

1.4 Pharmacodynamics (PD) and Pharmacokinetics (PK)

[Declare whether PD & PK studies (Section 2.3.3.1-3) have been provided.
[Briefly summarize any PD & PK data that have been submitted]

1.5 Occupational Health and Safety

[Declare whether OH&S information (Section 7) has been provided.
If not, justify why it is not required]
[Briefly summarize any OH&S data that has been submitted]

1.6 Environmental Safety

[Declare whether environmental safety information (Section 8) has been provided.
If not, justify why it is not required]
[Briefly summarize any environmental data that has been submitted]

1.7 Comparability data

Refer to section 2.2.1 on comparability exercise considerations

1.8 Special Data

[Declare whether a separate special data dossier(s) relating to genetically-modified organisms, has been provided.
[Briefly summarize any data on GMOs that have been submitted]

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.