FOOD AND DRUGS AUTHORITY

EMERGENCY USE AUTHORIZATION APPLICATION FORM FOR VACCINES AND BIOLOGICAL PRODUCTS

Document No.	: **FDA/SMC/BPD/AP-EVB/2021/12**
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FDA/SMC/BPD/AP-EVB/2021/12

THIS APPLICATION FORM SHOULD BE SUBMITTED IN DUPLICATE

ELECTRONIC COPIES AND BY A COMPETENT TECHNICAL OFFICER

Note: Samples and product documents (presented in Common Technical Document (CTD) format) should be forwarded to the FDA through the local agent; customs duty and clearance are to be effected by the applicant in all instances.

Cover letter addressed to:

THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS-ACCRA
GHANA.

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 Biological product/ Vaccine registered in other countries? (Yes/No)
If yes, list countries and registration numbers:
WHO Emergency Use Listing. (Yes/No)
WHO prequalification (PQ) status (please provide PQ date):
Pharmacological classification:
Pharmaceutical form:
Route of administration:
Concentration/Strength:
Appearance/ Colour:
Indication(s):
Other indication(s):
Category of distribution:
Proposed distribution network:
VVM type:
Country of origin:
Marketing authorization holder:

Marketing authorization number & date (country of origin)
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):
3. 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 (s):
Title and /or designation of contact person(s):
Postal address (local agent):
Street or physical address (local agent):
E-mail (local agent):
Telephone number (local agent):
Full name of Superintendent Pharmacist:
Registration number of Superintendent Pharmacist:
4. REFERENCE PRODUCT
State the rationale for the choice of reference product (if the product is a Biosimilar):

Reference product	Specification	Distinct Prescribed Uses

5. FORMULATION DETAILS

PROVIDE THE FULL DETAILS BELOW (EVERY CONSTITUENT MUST BE LISTED)

(a) Name of Biological active constituent	Specification			Concentration
	Reference standard	min	max	

(b) Non-biological active constituent name (if applicable)	Specification			Concentration	Purpose in formulation
	Reference standard	min	max		

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?

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 techniques, as well as all certificates to demonstrate the virus/pathogen-free status of the ingredient:
(Refer to Manufacturing process considerations (section 2.2.2))

6. MANUFACTURERS' DETAILS (FPP)

Company name Street address: E-mail: Telephone number:	

Company's registration number	
Street/physical address of manufacturing site	
Extent/Stage of manufacture (attach flow diagram)	

7. PROVIDE DETAILS OF RESPONSIBLE PERSON PERFORMING 'RELEASE FOR SUPPLY'

Name of responsible person:

Position:

Title:

Company name:

Street address:

E-mail:

Telephone number:

8. EVIDENCE OF GOOD MANUFACTURING PRACTICE

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.

9. 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.		
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	
Commercial Presentation: **Pack sizes** (in content volume; *e.g*. mL): Submit four (4) copies of the product label in the appropriate format in accordance with requirements.	
13. APPLICANT'S CHECKLIST (MUST BE COMPLETED)	
Tick the appropriate boxes to verify that required documentation is attached: ☐ Appropriate fee ☐ Application form completed and signed ☐ Completed batch release records, if applicable *(Refer to www.fdaghana.gov.gh for minimum batch release requirements for specific products)*	
14. DECLARATION (MUST BE COMPLETED)	

I declare that the information provided with this application is complete and correct.

Name: _____

Position/Designation: _____

Signature : _____ Date: _____

Official stamp:

False declaration may lead to prosecution.