

DRAFT



FOOD AND DRUGS AUTHORITY

VARIATION APPLICATION FORM FOR EMERGENCY USE AUTHORIZED VACCINES AND BIOLOGICAL PRODUCTS

Document No.	: FDA/SMC/BPD/AP-VAR/2021/13
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(This Application form is 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.**

SUBMISSION SHOULD ALWAYS BE DONE BY A COMPETENT TECHNICAL OFFICER

FDA EUA number: _____

1. Application details

Human

Veterinary

1.1 EUA Variation type: (tick as applicable options)

Minor variation (N)

Major variation (M)

Grouping of variations

Single variation

Grouped variations

1.2 Associated Finished Pharmaceutical Product (FPP) Name:

.....

1.3 Name and Address of Applicant:

Name	Address
	<p data-bbox="573 510 911 541"><i>Contact postal address:</i></p> <p data-bbox="573 724 781 756"><i>Contact email:</i></p> <p data-bbox="573 795 911 827"><i>Contact phone number:</i></p>

2.0 Summary of proposed changes

For multiple variations (grouped variations), reproduce this section and provide separate summaries for each proposed variation.

Variation(s) to:

- | | |
|---|---|
| <input type="checkbox"/> Administrative Information | <input type="checkbox"/> Efficacy |
| <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Safety |
| <input type="checkbox"/> Quality Control | <input type="checkbox"/> Other (s) For other (s) please provide details below |

2.1 Variation title and number:

2.2 Summary of current and proposed details:

Current details	Proposed details
I.	I.
II.	II.
III.	III.
IV.	IV.
V.	V.
VI.	VI.

2.3 Reason (s) for change (S):
(Clearly state the reason for change in detail)

I.
II.
III.
IV.
V.
VI.

2.4 Date of implementation.....

2.5 Documentation checklist

The following documents have been submitted together with this EUA variation application form:

<i>Note: All documents provided for this EUA variation application must be valid.</i>	
Supporting documentation <i>All supporting documents as stipulated for the change in the Guidance on the EUA Variation</i>	Yes <input type="checkbox"/>

4. Declaration

Please check all declarations that apply.

I declare that:

- For each change all conditions as stipulated in the *Guidance (Guidelines) on Variations to a Biological Product* for the change requested are fulfilled.
- There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.
- Where applicable, national (Variation) fees have been paid
- The information submitted is true and correct.

Name:

.....

Signature:Date: ____/____/____