

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR VARIATIONS TO A BIOLOGICAL PRODUCT**

**Document No. : FDA/SMC/BPD/AP-VAR/2015/05**

**Date of First Adoption :12th March, 2015**

**Effective Date :12th March,2015**

**Version No. :01**

**APPLICATION FORM FOR VARIATIONS TO A BIOLOGICAL PRODUCT**

*(To be submitted in duplicate, one comb-bound hard copy and one electronic copy)*

**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***

1. **Application details**

Human Veterinary

Current product FDA registration number: ………………………………………

**1.1 Variation type: (tick as applicable options)**

Minor variation (N) Major variation (M)

**1.2 Grouping of variations**

Single variation Grouped variations

**1.3 Associated Finished Pharmaceutical Product (FPP) Name:**

…………………………………………………………………………………………………………

**1.4 Name and Address of Applicant:**

|  |  |
| --- | --- |
| Name | Address |
|  | *Contact postal address:*  *Contact email:*  *Contact phone number:* |

**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:**

Administrative Information Efficacy

Manufacturing Annual variation for human influenza vaccines

Quality Control Other (s)

For other (s) please provide details below

Safety

**2.1 Variation title and number:**

**2.2 Summary of current and proposed details:**

|  |  |
| --- | --- |
| **Current details** | **Proposed details** |
|  |  |

**2.3 Reason for change:**

**2.4 Date of implementation: ……………………................................................................**

1. **Documentation checklist**

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

|  |  |
| --- | --- |
| *Note: All documents must be provided for this application to be valid.* |  |
| Supporting documentation  *All supporting documents as stipulated for the change in the Guidance on Variations to a Biological Product are included in this submission* | Yes |

**4. Declaration**

*Please check all declarations that apply.*

I declare that:

For each change all conditions as stipulated in the *Guidance 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 fees have been paid

The information submitted is true and correct.

Name: …………………………………………………………………………………………………

Signature: ………………………………………………Date: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_