## Variation to a Registered Vaccine for Humans Application Form: Major or Moderate

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

1. **APPLICATION DETAILS**

## Variation type: (tick all applicable options)

Moderate variation Major variation

## Grouping of variations

Single variation Grouped variations

## Associated Vaccine product name /NAFDAC Reg No:

*e.g.Ptegracocal Vaccine 0.5ml – A6 - 2019*

* 1. **Applicant details**

Please note that the contact listed in the table below will be the local representative authorized by the Vaccine product manufacturer (if different from the manufacturer) for communication for this specific application.

|  |  |
| --- | --- |
| **Applicant** |  |
|  |  |
| **Primary contact person responsible for this application** | Title:First name: Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Building/House No.** |  |
| **Road/Street** |  |
| **Town/City** |  |
| **District/LGA** |  |
| **State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

If there are other contacts who should be routinely copied into correspondence for this application they should also be listed below.

|  |  |
| --- | --- |
| **Applicant** |  |
|  |  |
| **Primary contact person responsible for this application** | Title:First name: Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Building/House No.** |  |
| **Road/Street** |  |
| **Town/City** |  |
| **LGA** |  |
| **State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

|  |  |
| --- | --- |
| **plicant** |  |
|  |  |
| **Primary contact person responsible for this application** | Title:First name: Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Building/House No.** |  |
| **Road/Street** |  |
| **Town/City** |  |
| **LGA** |  |
| **State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

1. **SUMMARY OF PROPOSED CHANGES**

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

## Variation title and number:

*e.g. Moderate variation # 30a:*

*Change involving an approved chemical/synthetic adjuvant —* change in supplier of a chemical synthetic adjuvant

## Summary of current and proposed details:

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

* 1. **Reason for change:**
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.** |  |
| Quality Information Summary (QIS)*For Vaccine Products that have an agreed upon QIS, the QIS should be revised and submitted with any revised sections highlighted. A QIS should be completed in its entirety (irrespective of the proposed change). It should include information on all strengths, with any changes highlighted (e.g. in red type).* | *Yes**No agreed QIS No change to QIS* |
| Supporting documentation*All supporting documents as stipulated for the change in the [NAFDAC GUIDELINES ON VARIATIONS TO A REGISTERED VACCINE FOR](https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/More_On_R_and_R/NAFDAC-Guidelines-on-Variations-to-a-Registered-Vaccine-for-Humans-1.pdf)**[HUMANS](https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/More_On_R_and_R/NAFDAC-Guidelines-on-Variations-to-a-Registered-Vaccine-for-Humans-1.pdf) are included in this submission* | *Yes* |

1. **DECLARATION**

# Please check all declarations that apply.

I declare that:

For each change all conditions as stipulated in the *Guidance on Variations to a Registered Vaccine for humans* 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.

The information submitted is true and correct.

Name:

Signature: Date: