



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

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

1.1 Variation type: (tick all applicable options)

☐ Moderate variation ☐ Major variation

1.2 Grouping of variations

☐ Single variation ☐ Grouped variations

1.3 Associated Vaccine product name /NAFDAC Reg No:

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

1.4 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.



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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	



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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	
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2. SUMMARY OF PROPOSED CHANGES

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

2.1 Variation title and number:

e.g. Moderate variation # 30a:

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



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2.2 Summary of current and proposed details:

Current details	Proposed details

2.3 Reason for change:

3. 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) <i>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).</i>	☐ Yes ☐ No agreed QIS ☐ No change to QIS
Supporting documentation <i>All supporting documents as stipulated for the change in the NAFDAC GUIDELINES ON VARIATIONS TO A REGISTERED VACCINE FOR HUMANS are included in this submission</i>	Yes



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4. DECLARATION

Please check all declarations that apply.

I declare that:

- ☐ For each change all conditions as stipulated in the *Guidelines 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: _____