



APPLICATION FOR VARIATION

ACKNOWLEDGEMENT

The Food and Drugs Authority (FDA) acknowledges the technical support of the World Health Organization (WHO) in the development of this guideline.

The Food and Drugs Authority (FDA) is grateful to the WHO for allowing it to adopt sections of the WHO guidelines on variation in developing this guideline.

Variation to a Registered Finished Medicinal Product

Application form

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)

Immediate notification (IN) Minor variation (Vmin) Major variation (Vmaj)

1.2 Grouping of variations

Single variation Grouped variations

1.3 Associated Finished Pharmaceutical Product (FPP) Name:

1.4 Name and Address of Applicant:

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. *Minor variation # 30:*

Minor change in the manufacture of the finished product

2.2 Summary of current and proposed details:

Current details	Proposed details

2.3 Reason for change:

2.4 Date of implementation (for Immediate Notifications only):

3. Documentation checklist

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

<i>Note: All documents must be provided for this application to be valid.</i>	
Supporting documentation <i>All supporting documents as stipulated for the change in the Guidance on Variations to a Prequalified Product are included in this submission</i>	<input type="checkbox"/> Yes

4. Declaration

Please check all declarations that apply.

I declare that:

- For each change all conditions as stipulated in the *Variation Guidelines for Allopathic Medicines* 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: _____