National Drug Authority
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Application for Variation to a Registered Pharmaceutical Product

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

1. Application details

1.1 Variation type: (tick all applicable options)

☐ Annual notification (AN) ☐ Immediate notification (IN)

☐ Minor variation (Vmin) ☐ Major variation (Vmaj)

1.2 Grouping of variations

☐ Single variation ☐ Grouped variations

1.3Finished Pharmaceutical Product (FPP) Name - Registration and File Numbers:

e.g. Isoniazid Tablets 100mg – 0000/06/1997, A000

1.4Applicant details

Applicant[1] **(Marketing Authorisation Holder)**	
Contact person responsible for this application	Title/Designation: First name: Surname name:

[1] ***Applicant***
An applicant is a person who applies for registration of a medicinal product to NDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person to register the medicinal product on his behalf, then Powers of Attorney, duly notarised in the country of origin, and registered with the Registrar of Companies in Uganda shall be provided. After the product is registered, the applicant shall be the ***Marketing Authorisation Holder (MAH)****.*

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Contact person's job title	
Contact person's postal address	
Contact person's email address	
Contact person's phone number	

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 # 30a:*
Change in batch size of the finished product - Up to and including a factor of ten (10) compared to the biobatch

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:

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Note: All documents must be provided for this application to be valid.	
Quality Information Summary (QIS)- (Only for registered pharmaceutical products for human use) *For FPPs 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 (regardless 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 Guidelines on Variations to a Registered Pharmaceutical Product for Human use are included in this submission*	☐ *Yes*

4. Declaration *(by Marketing Authorisation Holder)*.

Please check all declarations that apply.

I declare that:

☐ For each change all conditions as stipulated in the ***NDA Guidelines on Variations to a Registered Pharmaceutical Product for Human use, number DAR/GDL/005*** 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:

_____Tilte/Designation_____

Signature: _____ Date: _____