*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)**

Annual notification (M1)  Immediate notification (H2)

Minor variation (M3)  Major variation (Vmaj)

**1.2 Grouping of variations** *(acceptable ONLY when variations are consequential to each other)*

Single variation  Grouped variations

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

*e.g. Isoniazid Tablets NDA/MAL/HDP/XXXX, A000*

**1.4 Applicant details**

|  |  |
| --- | --- |
| **Applicant[[1]](#footnote-1)**  **(Holder of a Certificate of Registration)** |  |
| Contact person responsible for this application | Title/Designation:  First name:  Surname name: |
| 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:

|  |  |
| --- | --- |
| *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,******Doc. No. PAR/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: \_\_\_\_\_\_\_\_\_\_\_\_\_

1. ***Applicant***

   *An applicant is a person who applies for registration of a pharmaceutical product to NDA. The applicant may be the patent holder; a licensed person; the manufacturer; or an agent authorised by the manufacturer or patent holder.The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person to register the pharmaceutical 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* ***Holder of a Certificate of Registration****.*  [↑](#footnote-ref-1)