**APPLICATION FOR VARIATION OF REGISTERED TRADITIONAL AND HEALTH SUPPLEMENTPRODUCTS**

Instructions:

1. Please refer to **Appendix 12** of the Drug Registration Guidance Document (DRGD) for the conditions and supporting documents required for variation application.
2. Submission of relevant revised draft of package insert and labeling is subject to current regulatory requirements as per the latest Drug Registration Guidance Document (DRGD) and Circulars from NPCB.
3. The completed form must be

|  |  |  |
| --- | --- | --- |
| **Quest 2 &****Quest 3** | submitted to : | **SeksyenUbatKomplementari**, Pusat PendaftaranProduk, Biro PengawalanFarmaseutikalKebangsaan, KementerianKesihatan Malaysia, Lot 36, JalanUniversiti, 46200 Petaling Jaya, Selangor  |

1. Incomplete submission will be rejected.

|  |  |  |
| --- | --- | --- |
| Product Category:  | * Traditional
* Health Supplement
 | * Quest 2
* Quest 3
 |
| Product name: |  |
| Product registration holder: |  |
| Reference no.: |  | MAL No. |  |

**Tick ( ✓ ) on the variation changes required. Multiple selectionsare allowed.**

|  |  |  |
| --- | --- | --- |
| No. | **MINOR VARIATION** | Tick |
|  | Change in name of manufacturer and/or other manufacturers without any change in address of site. |  |
|  | Replacement, addition or deletion of company logo on the packaging component. (without any changes on graphic and label content) |  |
|  | Change in product owner. |  |
|  | Change in importer/ store address. |  |
|  | Change or addition of imprints, bossing or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for productmarking. |  |
|  | Change in shape or dimensions of the container or closure. |  |
|  | Change in pack size of the drug product (Finished product), without change in primary packaging material. |  |
| Change in the number or units (e.g. tablets) in a pack. |  |
|  | Tightening of specification limits of the product (finished product) and/or active ingredient. |  |
|  | Change in particulars of the manufacturer of an active ingredient without any change in specification.1. Change in manufacturer of active ingredient
 |  |
| 1. Addition of manufacturer of active ingredient
 |  |
| 1. Change in name and/or rephrasing of address of a manufacturer of active ingredient
 |  |
|  | Change in secondary packaging material (or change in any part of the primary packaging material that is not in contact with the finished product ) |  |
|  | **MAJOR VARIATION** |  |
|  | Change of product name. |  |
|  | Change in content of leaflet or prescribing information/ PIL. |  |
|  | Change in content of label inclusive of change in graphics/ artwork. |  |
|  | Change in manufacturing process of the finished product. |  |
|  | Change in overage of the active ingredient. (only applicable to Health Supplement) |  |
|  | Replacement of an EXCIPIENT with a comparable excipient and/or change in content of excipient. |  |
|  | Change in batch size. |  |
|  | Change in hard capsule shell. (colour, size or source) |  |
|  | Change in finished product or active ingredient specification. (includes addition of a new test parameter) |  |
|  | Change to in-process tests or limits applied during manufacture of the product.  |  |
|  | Change or addition in primary packaging material. |  |
|  | Change in shelf life of finished product:-a) As packaged for sale |  |
| b) After first opening |  |
| c) After dilution/ reconstitution |  |
|  | Change in storage conditions. |  |
|  | Appointment, deletion or change of OTHER manufacturers. |  |
|  | Addition or deletion of scoring/ break line on tablet. |  |
|  | Change in test procedure or analytical protocols of finished product. |  |

**Kindly specify the ALL the affected fields and their relevant details using the format below, in a Microsoft Word document (Font size:12). Kindly attach this document during the variation application.**

|  |
| --- |
| **Table 1** |
| **Field** | **Existing data** | **Proposed change data** | **Reason for changing** |
|  |  |  |  |
|  |  |  |  |

**Tick ( ✓ ) on the documents attached. Multiple selections are allowed.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Field** | **ATTACHED SUPPORTING DOCUMENTS**  | Tick |
| No. | **Quest 2** | **Quest 3** |  |  |
|  | A1 | F12 | Letter of Authorization from Product Holder (For Variation of Product Name only) |  |
|  | A3.2 | A3.2 | CoA Of Capsule Shell/ TSE/BSE Free Certificate |  |
|  | B1.2 | B1.4 | Batch Manufacturing Formula |  |
|  | B2.2 | B2.2 | Manufacturing Process Documentation |  |
|  | B3 | B3 | In Process Quality Control |  |
|  | B4 | B4 | Finished Product Specification Documentation |  |
|  | B5 | B5 | Stability Data |  |
|  | C | C | Attachment Container Type |  |
|  | D1 | D1 | **Proposed** and**Current Existing** Labels For Immediate Container |  |
|  | D2 | D2 | **Proposed** and**Current Existing** Labels For Outer Carton |  |
|  | D3 | D3 | **Proposed** and**Current Existing** Package Inserts |  |
|  | F1 | F1 | Letter Of Authorization From Product Owner |  |
|  | F2.1 | F2.1 | Letter Of Appointment Of Contract Manufacturer From Product Owner |  |
|  | F2.2 | F2.2 | Letter Of Acceptance From Contract Manufacturer |  |
|  | F6 | F6 | GMP Of Foreign Manufacturers |  |
|  | F12 | F12 | Other Supporting Documentations; Please Specify…………………………………………………………………………………….……………………………………………………………………………………. |  |
|  |  |  | Print form of product (only applicable to Quest 3 product) |  |

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| APPLICANT DECLARATION |
|  |
| Signature of Applicant |  |
| Full name of Applicant |  |
| Identification Card No. |  |
| Title/ Position in Company |  |
| Telephone No. |  | Date of Application |  |
| Email address |  |
| Company nameCompany Official Stamp |  |