Product Registration Holder (PRH) Letterhead

Date:

Our Ref:

Head of \_\_\_\_\_\_\_\_\_ Section (\*refer to product category)

Centre of Product Evaluation & Cosmetic

National Pharmaceutical Regulatory Agency

Ministry of Health Malaysia

Lot 36, Jalan Universiti

46730 Petaling Jaya, Selangor

Dear Sir/ Madam,

**DECLARATION LETTER FOR APPROVED ACTIVE PHARMACEUTICAL INGREDIENTS (API) IN NEW PRODUCT APPLICATION**

**New Product Name :**

**Call No. :**

**API Name:**

**API Manufacturer :**

**Product Manufacturer :**

**Submission Option : DMF / ACTD / CEP**

**DMF Version Number :**

Registered Product Containing the Approved API:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Name of Registered Product  | Product Manufacturer | MAL No. | API Submission Option  |
| 1 |  |  |  |  |
| 2 |  |  |  |  |

I hereby declare that:

1. The API information Submitted in Part II S of Quest 3+ for the New Product Application has been updated with the following information:

* All additional information previously requested during evaluation

*Attachment I: List of additional data which has been requested during previous submission (Approved API)*

* All approved variation applications

*Attachment II: List of Approved Variation Application*

* No changes other than above OR
* Summary of changes (other than above)

 *Attachment III: Table of comparison (Approved API and New submission)*

2. The API in the new product and the registered product are manufactured at the same manufacturing site(s) with the same synthesis/manufacturing process.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature)

Name:

Designation:

Company Name & Address:

Contact Number:

Email address:

Active Pharmaceutical Ingredient Manufacturer Letterhead (For DMF option only)

Date:

Our Ref:

Head of \_\_\_\_\_\_\_\_\_ Section (\*refer to product category)

Centre of Product Evaluation & Cosmetic

National Pharmaceutical Regulatory Agency

Ministry of Health Malaysia

Lot 36, Jalan Universiti

46730 Petaling Jaya, Selangor

Malaysia

Dear Sir/ Madam,

**DECLARATION LETTER FOR APPROVED ACTIVE PHARMACEUTICAL INGREDIENTS (API) IN NEW PRODUCT APPLICATION**

**New Product Name :**

**Call No. :**

**API Name :**

**API Manufacturer :**

**Product Manufacturer :**

**DMF Version Number :**

Registered Product Containing the Approved API:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Name of Registered Product  | Product Manufacturer | MAL No. | API Submission Option  |
| 1 |  |  |  |  |
| 2 |  |  |  |  |

I hereby declare that:

1. The Drug Master File (DMF) has been updated with the following information:

* All additional information previously requested during evaluation.

*Attachment I: List of additional data which has been requested during previous submission*

*(Approved API)*

* All approved variation applications

*Attachment II: List of Approved Variation Application*

* No changes other than above and the latest DMF has already been submitted to NPRA

DMF Version No.:

* Summary of other Changes

 *Attachment III: Table of comparison (Approved API and New submission)*

New DMF Version No:

2. The API in the new product and the registered product are manufactured at the same manufacturing site(s) with the same synthesis/manufacturing process.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature)

Name:

Designation:

Company Name & Address:

Contact Number:

Email address:

*Attachment I*

**List of Additional Data Which Has Been Requested During Previous Submission (Approved API)**

Correspondence I

Date of ‘*Surat Maklumat Data Tambahan Penilaian API’*: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Correspondence 2 (if Applicable)

Date of email requesting additional information: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Correspondence 3 (if Applicable)

Date of email requesting additional information: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Correspondence 4 (if Applicable)

Date of email requesting additional information: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Correspondence 5 (if Applicable)

Date of email requesting additional information: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1 Name of attachment shall be clear for ease of reference;

e.g. Additional Info from Query(1)\_01/01/2010

2 Supporting documents (limited to TWO attachments per correspondence):

* List of additional information requested by NPRA
* Response provided by API manufacturer, along with all the annexes
* Satisfactory notification for API evaluation (if available)

*Attachment II*

**List of Approved Variation Application**

Variation I

Type of Variation Approved: [Type here]

Date of Approval: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Variation 2

Type of Variation Approved: [Type here]

Date of Approval: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Variation 3

Type of Variation Approved: [Type here]

Date of Approval: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

Variation XXXXX

Type of Variation Approved: [Type here]

Date of Approval: [Type here]

Name1 of attachment2 uploaded to S10 of Quest 3+: [Type here]

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1 Name of attachment shall be clear for ease of reference; e.g. Variation(1)\_01/01/2010

2 Supporting documents (limited to TWO attachments per correspondence):

* List of additional information requested by NPRA
* Response provided, together with all the annexes
* Variation approval letter

*Attachment III*

**Summary of Other Changes: Table of comparison (Approved API and New submission)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **Field in Part II S** | **Approved API** | **New Submission** | **Remarks** |
|  |  |  |  |  |
|  |  |  |  |  |