Product Registration Holder (PRH) Letterhead

Date:
Our Ref:

Head of Active Pharmaceutical Ingredient (API) Section
Centre of Product Registration
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia
Lot 36, Jalan Universiti
46200 Petaling Jaya, Selangor

Dear Sir/ Madam,

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

New Product Name :
Call No. :
API Name:
API Manufacturer :
Product Manufacturer :
Submission Option : DMF / ACTD / CEP
DMF Version Number :
CEP Number :

Registered Product Containing the Approved API:

No.	Name of Registered Product	Product Manufacturer	MAL No.	API Submission Option
1				**DMF / ACTD / CEP**
2				**DMF / ACTD / CEP**

I hereby declare that:

1. The API information Submitted in Part II S of QUEST3+ 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. (If Yes, please refer below)

- ☐ There are changes other than above. Summary of changes provided as in Attachment III.
  Attachment III: Table of comparison (Approved API and New submission API)

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

_____
(Signature)
Name:
Designation:
Company Name & Address:
Contact Number:
Email address:

Date:
Our Ref:

Head of Active Pharmaceutical Ingredient (API) Section
Centre of Product Registration
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia
Lot 36, Jalan Universiti
46200 Petaling Jaya, Selangor
Malaysia

Dear Sir/ Madam,

DECLARATION LETTER FOR APPROVED ACTIVE PHARMACEUTICAL INGREDIENT (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				**DMF / ACTD / CEP**

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.:

- ☐ There are changes other than above. Summary of changes provided as in Attachment III.
  Attachment III: Table of comparison (Approved API and New submission API)
  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 and 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]
Name[1] of attachment[2] uploaded to S10 of QUEST3+: [Type here]

Correspondence 2 (if Applicable)
Date of email/ correspondence requesting additional information: [Type here]
Name[1] of attachment[2] uploaded to S10 of QUEST3+: [Type here]

Correspondence 3 (if Applicable)
Date of email/ correspondence requesting additional information: [Type here]
Name[1] of attachment[2] uploaded to S10 of QUEST3+: [Type here]

Correspondence 4 (if Applicable)
Date of email/ correspondence requesting additional information: [Type here]
Name[1] of attachment[2] uploaded to S10 of QUEST3+: [Type here]

Correspondence 5 (if Applicable)
Date of email/ correspondence requesting additional information: [Type here]
Name[1] of attachment[2] uploaded to S10 of QUEST3+: [Type here]

Note:
Date of correspondence applicable for new product application submitted through QUEST3+ i.e application Reference No. starts from 2017XXXX

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[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]
Name[1] of attachment[2] uploaded to S10 of Quest 3+: [Type here]

Variation 2
Type of Variation Approved: [Type here]
Date of Approval: [Type here]
Name[1] of attachment[2] uploaded to S10 of Quest 3+: [Type here]

Variation 3
Type of Variation Approved: [Type here]
Date of Approval: [Type here]
Name[1] of attachment[2] uploaded to S10 of Quest 3+: [Type here]

Variation XXXXX
Type of Variation Approved: [Type here]
Date of Approval: [Type here]
Name[1] of attachment[2] uploaded to S10 of Quest 3+: [Type here]

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[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