Our Ref:

Head of \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Section

Centre of Product and Cosmetic Evaluation

National Pharmaceutical Regulatory Agency

Ministry of Health Malaysia

Lot 36, Jalan Universiti

46200 Petaling Jaya

Malaysia

Dear Sir/ Madam,

**SUBMISSION OF DRUG MASTER FILE (DMF) FOR PRODUCT REGISTRATION APPLICATION TO NATIONAL PHARMACEUTICAL REGULATORY AGENCY**

|  |  |
| --- | --- |
| **Product Name** | **:** |
| **Active Pharmaceutical Ingredient** | **:** |
| **API Manufacturer’s Name** | **:** |
| **API Manufacturer’s Address** | **:** |
| **Product Registration Holder** | **:** |
| **Product Category** | **: 🞏 NCE** **🞏 Generic/ Prescription** |
| **DMF Version Number** | **:**  |

The aforementioned Drug Master File Holder herewith submits the Drug Master File to National Pharmaceutical Regulatory Agency (NPRA) to refer and review the above mentioned DMF in support of the submission of product registration mentioned.

If you need any further clarification, feel free to contact us at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (email address).

Thank you.

Sincerely,

\_\_\_\_ (Signature) \_\_\_\_\_\_\_\_\_\_ \_

Name:

Designation:

Email address:

Date: