Company letterhead

Date

The Registrar of Medicines **CODE** (Refer General Information guideline section 13)

Department of Health

Private bag X828

Pretoria

0001

Attention:

**Dear Madam/Sir**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Product Proprietary Name** | | |  | | | |
| Application Number | | |  | | | |
| Registered medicine |  | Old medicine | |  | Reply to MCC Response |  |

**1 Attached herewith:**

|  |  |
| --- | --- |
| **Original medicine registration certificate\*** |  |
| If already submitted: Application………. Dated……… Reference No……….. |  |
| **Administrative amendment fee, if relevant** |  |
| **Registration certificate amendment fee, if relevant** |  |

*\* Certified copy of original may be submitted on submission of amendment, with amended certificate only being issued on approval of amendment and submission of original certificate.*

**2 This amendment involves:** (specify the amendments, Type and category number e.g.

container amendments Type B Category 3

formulation change Type B Category 8

or

additional manufacturer Type C Category 26

final product specification amendments Type C Category 4

shelf-life extension Type C Category 10)

**and the following supporting documentation is provided:**

*(Items not applicable to the submission may be omitted providing the omission is confirmed/identified)*

|  |  |
| --- | --- |
| **AMENDMENTS NOT AFFECTING THE MEDICINE REGISTRATION CERTIFICATE** | |
|  |  |
| **Pharmaceutical and analytical** |  |
| Updated PART 1Ac) Amendment history / Module 1.2.1 f) |  |
| Other documents as reflected under the specific amendments |  |