**Cover Letter**

[Insert date]

**Attention:**

[Insert name]

[Insert address]

**Subject:** [Insert subject line]

Dear Sir/Madam,

We are pleased to submit a [insert application type, such as ‘Marketing Authorization Application’] for the registration of [insert product name], see product details below. [Product name] has [insert approval type, such as ‘Stringent Regulatory Approval by United States Food and Drug Administration’] under the brand name [insert brand name with SRA approval’].

|  |  |
| --- | --- |
| **Name of the [insert ‘pharmaceutical’ or ‘medical device’] product:** | [Name of the product] |
| **Pharmaceutical form(s) and strength(s):** | [Pharmaceutical form(s) and strength(s) only for pharmaceutical products] |
| **INN/Active Pharmaceutical Ingredient(s):** | [INN/APIs] |
| **Indication(s):** | [Indication(s)] |

You will find enclosed the submission dossier as specified hereafter:

1. [List the cover letter requirements from the guidelines]
2. [This will likely include types of documents (soft copy, CD rom), electronic submission confirmation, statement on payment of fees, etc.]

I trust this application meets your favorable opinion.

Sincerely,

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

[Signature]

[Name]

[Title]

[Phone number(s)]

[Email address]

[company stamp, if required]