< Applicant> < Address>

<Postal Code>

< Town>

<Country>

<Date>

<Rwanda FDA>

<P.O.BOX 1948> <Kigali>

< Rwanda >

Dear Sir/Madam,

**Subject: Submission of Application Dossier(s) for Marketing Authorization of <Product Name(s), [strength(s)] of active pharmaceutical ingredient(s) and dosage form(s)**

We are pleased to submit our Application Dossier(s) for a registration of human medicines that details are as follows:

**Name of the medicinal product(s):** ………………………………….…………………………

**Pharmaceutical form(s) and strength(s):** …………………………………………….………..

**INN/Active Pharmaceutical ingredient(s):** ……………………....................................................

**ATC Code(s):** ………….…………………………………………………………………………

You will find enclosed the submission dossier as specified hereafter:

 CTD format, 2 soft copies documents format

 The relevant fees for this application have been paid.

 CD rom/external driver that contains summaries in word format and body data in PDF format



 We confirm that all future submissions for this specific product will be submitted in this same format



We confirm that the electronic submission has been checked with up-to-date and state-of-the-art antivirus software.



 The electronic submission contains the following modules:



Module 1: Administrative information and product information

1. Module 2: Overview and summaries
2. Module 3: Quality
3. Module 4: Non clinical study reports
4. Module 5: Clinical study reports

 Type of Submission: 󠇯󠇯Full Application 󠇯󠇯Abridged Application

 I confirm that the Product Dossier information submitted including composition, formulation, strength, specifications and packaging is the same in all aspects as the product registered with the relevant SRA, WHO PQ and EAC (Only for Abridged Application)

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>