<Applicant>

<Address>

<Address>

<Post code> <Town>

<Country

<Date>

Rwanda Food and Drugs Authority

P.O.Box 84 Kigali

Rwanda

Dear Sir/Madam,

**Subject:** **Authorization to access Active Pharmaceutical Ingredient Master File**

Reference is made to the above subject matter.

Consent is hereby granted to Rwanda FDA to make reference to this company's Active Pharmaceutical Ingredient Master File(s) for [API(s) name] in the evaluation of applications relating to the registration of [medicine name(s)] submitted to Rwanda FDA by the (applicant’s name).

This consent does/does not include authorization to supply information or extracts from or the whole of the data to:

(Name of company or individual)

The substance is manufactured by:

(Names and addresses of all manufacturing sites and manufacturing steps carried out at site)

A copy of the *applicant’s Part of the APIMF* as specified in the Active Pharmaceutical Ingredient Master File Procedure has been supplied to the applicant.

A formal agreement exists between the applicant of the medicine and the manufacturer of the API, which ensures that information will be communicated between them and to Rwanda FDA before any significant change is made to the site of manufacture, manufacturing procedure or quality control specifications of the API. Except as permitted by the Rwanda FDAguidelines relating to changes to medicines, such changes will not be made to the API to be used in manufacture of the medicine destined to be distributed in Rwanda before written approval is granted by the Rwanda FDA.

I understand that the consequences of failure to obtain approval for changes where approval is necessary may include de-registration and recall of batches of medicines.

This APIMF (or data identical to that contained therein) has also been submitted to and approved by the regulatory authorities in (*list of countries with stringent regulatory systems*), and Rwanda FDA is authorized to request and refer to the evaluation reports of these agencies.

Rwanda FDA is also authorized to exchange its own evaluation reports with these and other regulatory authorities.

Any questions arising from Rwanda FDA’s evaluation of this APIMF should be forwarded to:

{Name and address}

Yours faithfully

{Signature of Company Representative}

{Name}

{Position in Company}

{Date}