**ACTIVE PHARMACEUTICAL INGREDIENT MASTER FILE**

The Secretary to the Authority

National Drug Authority

P. O. Box 23096 Kampala

**Uganda**

Dear Sir/Madam

**Authorisation to access Active Pharmaceutical Ingredient Master File (APIMF)**

Consent is hereby granted to National Drug Authority (NDA) to make reference to {APIMF holder’s name}’s APIMF for {API name} in the evaluation of applications relating to {FPP name(s)} submitted to NDA by {applicant’s name}.

This consent does/does not include authorisation 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 NDA APIMF procedure has been supplied to the applicant of the VPP.

A formal agreement exists between the applicant of the VPP and the manufacturer of the API which ensures that information will be communicated between them and to NDA before any significant change is made to the site of manufacture, manufacturing procedure or quality control specifications of the API. Except as permitted by NDA’s *Guidelines on Variations to Registered Pharmaceutical Products for Veterinary Use****,*** such changes will not be made to the API to be used in manufacture of the VPP destined to be distributed in Uganda before written approval is granted by NDA.

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 NDA is authorised to request and refer to the evaluation reports of these agencies. NDA is also authorised to exchange its own evaluation reports with these and other regulatory authorities.

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

{Name and address}

Yours faithfully

{Signature of Company Representative} {Name}

{Position in Company}

{Date}

**CERTIFICATE OF SUITABILITY TO THE MONOGRAPHS OF THE EUROPEAN PHARMACOPOEIA**

The Secretary to the Authority,

National Drug Authority

P. O. Box 23096 Kampala

Uganda

Dear Sir/Madam

**Authorisation to access the Certificate of Suitability to the Monographs of the European Pharmacopoeia (CEP)**

Consent is hereby granted to National Drug Authority (NDA) to make reference to CEP No. {Certificate number and version} issued by the European Directorate for the Quality of Medicines (EDQM) on {date of issue} for {CEP holder’s name}’s {drug substance name} in the evaluation of applications and relating to the registration of {FPP name(s)} submitted to NDA by the applicant {applicant’s name}.

The substance is manufactured by:

{Names and addresses of all manufacturing sites, and manufacturing steps carried out at site}

Assurance is given that any conditions or additional testing requirements attached to the Certificate by the EDQM will be complied with for any batch of the API to be used in manufacture of FPPs to be distributed in Uganda.

A formal agreement exists between the applicant of the FPP and the manufacturer of the API which ensures that information will be communicated between them and to NDA before any significant change is made to the site of manufacture, manufacturing procedure or quality control specifications of the API. Except as permitted by NDA’s *Guidelines on Variations to Registered Pharmaceutical Products for Veterinary Use****,*** such changes will not be made to API to be used in manufacture of FPPs destined to be distributed in Uganda before written approval is granted by NDA.

Where relevant, any revised Certificates for this API will be forwarded to NDA for its information and records.

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 FPPs containing this material in Uganda.

Any questions arising from evaluation of this API should be forwarded to:

{Name and address}

Yours faithfully

{Signature of Company Representative} {Name}

{Position in Company}

{Date}