<TEMPLATE>

LETTER OF ACCESS FOR APIMF

<Active Pharmaceutical Ingredient Master File (APIMF)>
<Letter of Access (LOA)>

<Date

<Active pharmaceutical ingredient name :>

<APIMF Holders name and address :>

<Active pharmaceutical ingredient manufacturing site(s) :>

<APIMF version number :>

<Open part :>

<Closed Part :>

< {APIMF Holders Name}, hereby authorizes the relevant NAFDAC staff members and external experts to refer to and review the above-mentioned APIMF (and subsequent versions) in support of application(s) submitted by {Applicants Name/Address} for the following product>

< *(FPP product generic name), (strength) and (dosage form)* (NAFDAC- Assigned reference number if known)>

<The aforementioned active pharmaceutical ingredient master file holder is committed to ensuring batch-to-batch consistency and to informing {Applicants Name} and NAFDAC of any change in the Open or Closed parts of the APIMF before any significant change is made to the site of manufacture, manufacturing procedure or quality control specifications of the API. Except as permitted by NAFDAC guidelines 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 Nigeria before written approval is granted by NAFDAC.

It is understood that the consequences of failure to obtain approval for changes where approval is necessary may include de-registration and recall of batches of medicines.>
<Name & Signature of Responsible Officer>
<Designation>
<Name and Address of APIMF Holder>