SAMPLE LETTER OF ACCESS FOR DMF
(< FROM DRUG MASTER FILE HOLDER ON HEADED PAPER>)

Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667

[DD-MM-YYYY]

Number of Drug Master File: <015:001> / New DMF (delete as appropriate)

Name of Drug Substance: DRUG SUBSTANCE A
Drug Master File holder:

ABC PTE LTD
DEF Lane 1
GHI City
Singapore 100000

We, the Drug Master File holder, hereby authorise the Health Sciences Authority to refer to and review the above mentioned Drug Master File in support of the following product registration application:

Name of Product: AAA XYZ Tablet 10MG

Name, Address and Email contact of Product Registrant:

XYZ PTE LTD
XXX Industry Park
#01-01
Singapore 200000
Email: xxxxxx@xyz.sg

We, the Drug Master File holder, hereby commit to ensure batch to batch consistency and to inform XYZ PTE LTD and Health Sciences Authority of any change in the drug substance specification, in the manufacturing process or any other changes that will likely affect the product's quality or safety.

Signature for the Drug Master File holder
[Name and function]
[Signature]
[Email address]