**Letter of Access (LOA) from the manufacturer of the active substance or ASMF holder permitting the Thai license holder to use the ASMF**

Medicines Regulation Division

Thai Food and Drug Administration

88/24 Tiwanon Road, Nonthaburi

11000 THAILAND

...............[Date]..................

Name of Active Substance: [active substance name]

Active Substance Master File holder: [name and address]

Active Substance Master File Reference number issued by Thai FDA: [XXXXXXXX]

e-identifier number issued by Thai FDA: [XXXXXXXX]

The aforementioned Active Substance Master File holder hereby authorizes the Medicines Regulation Division, Thai Food and Drug Administration, including internal reviewers and experts to refer and review the above mentioned Active Substance Master File in support of the following drug registration application(s) or variation of drug registration application(s)

Medicinal product: [Name of the medicinal product]

e-identifier number of medicinal product: [XXXXXXXX]

Thai license holder name: [Name of Thai license holder]

Yours sincerely

[Signature of the Active Substance Master File holder]

[Name and Position]

[contact information]