FORM-6

[(See rule 7(16)]

PROVISIONAL CERTIFICATE FOR ENLISTMENT AS MANUFACTURER/ IMPORTER

E.No. …….. Dated: ……..……..
M/s……..…….located at the address ……...……is Agent of ……(applicable for importer only)

Is hereby enlisted in the enlistment register as manufacturer/ importer by the Authority subject to the following conditions namely:-

a. The manufacturer or importer shall be responsible for the quality, efficacy and safety of all the therapeutic goods manufactured and sold by him.

b. He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, (XXI) of 2012 except those exempted under the said Act.

c. He shall immediately recall the defected therapeutic goods within 15 days after intimation to him and report the compliance to the Authority.

d. He shall be responsible to withdraw the unsafe therapeutic goods from the market if so declared by the Authority. He shall also report adverse affect reports, (if any), to the Authority within 15 days period and notify focal person for such reporting.

e. Any other relevant condition imposed by the Authority in future.

f. This certificate shall not be valid after the date notified by the Authority through official gazette.

g. Certificate of enlistment shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

Designated Officer …….
Dated..... Division of Health and OTC Products
Drug Regulatory Authority of Pakistan