FORM-7

[(See rule 7(17)]

PROVISIONAL CERTIFICATE FOR ENLISTMENT OF PRODUCTS

Following products of M/s……located at the address ……..……is / are manufactured by ……..……..

EN	Brand name of the product				
	List of ingredients With strength	Common Name of ingredients	Recommended use	Pack size	Maximum Retail price

Conditions for Enlistment:

a) The product(s) shall be tested for microbial contamination and it is verified that these products does not contain any type of pathogenic microbial contamination.

   Provided that disinfectants and homeopathic medicines containing 50% or above concentration of ethanol shall be exempted from such microbial testing.

b) The content the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

c) The product shall not contain any toxic or dangerous materials which are injurious to health.

d) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

e) The products shall remain safe, effective and retain its quality during the whole shelf life.

f) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI) of 2012.

g) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

h) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

i) The manufacturer/ importer shall be responsible for all the liabilities or damage occurred due to usage of enlisted products.

j) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

k) Label claim of prohibited diseases shall not be made in any case, as required under the rules.

l) Maximum Retail Price (MRP) shall be as per policy finalized by the Authority.

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

n) 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.

o) Recommended conditions for use as per standard package insert or leaflet shall be reviewed by the Authority which shall be part of finished product label.

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