FORM-5

[(See rule 3(3)]

APPLICATION FOR ENLISTMENT OF NEW MEDICINE (NEW FORMULATIONS) OR IMPORTED PRODUCTS

(Attach readable soft copy with application)

I/We……..… Owner (s) of M/s……hereby apply for enlistment of following products manufactured by M/s…….…… situated at……city……..…. province……..……. Country of origin of principal manufacturer……. firm/company from (has already applied as importer) located at the premises as above

1. Product Profile

S.NO	Brand Name of Product.				
	Common Name ingredients	List of ingredients with strength	Recommended conditions for use	Pack size	Maximum Retail price

2. Batch manufacturing formula or Master Formulation.
3. Manufacturing process and In-process controls.
3. Testing specifications of starting materials and finished products, validation data and certificates of analysis.
4. Shelf life and storage. (Evidence of long term and accelerated Stability data)
5. Recommended conditions for use (with evidence of quality, safety and efficacy data).
6. Evidence of clinical safety and efficacy based on Pre-clinical and clinical studies along with data.
7. Packaging and labeling (label mock up and package leaflet insert approved in the country of origin.
8. Maximum Retail price.
9. Import documents
    a. Manufacturing license of the Principal Manufacturer in the country of origin.
    b. Approval of product registration or marketing authorization in the

country of origin.

c. G.M.P Certificate of Principal Manufacturer by the local regulatory Authority.
d. Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
e. Certification with any Organization or Authority.
f. Certificate of Analysis of active ingredients and finished products from the (preferably from Public Sector Laboratory or Independent Accredited Lab).
g. Last three years commercial invoices.
h. Bill of lading and transport documents.
i. Tax or duties payment evidence.
j. Agreement between the importer and principal manufacturer.
k. Last inspection report by the local regulatory Authority.
l. State countries with evidence where product is approved/available/submitted for approval/rejected and approved recommended conditions for use (attach evidence).

10. Fee deposit receipt.

11. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

Name of the owner

Signature

Seal of the Firm/ Company.

Dated.....