DOCUMENTS / INFORMATION REQUIRED FOR RENEWAL OF DRUG MANUFACTURING LICENSE

i). Properly filled in application made to CLB/Licensing Division well before expiry of DML on Form 1-A as prescribed vide schedule A of Drugs (Licensing, Registering & Advertising) Rules 1976 along-with all required documents. The prescribed Form 1-A is reproduced as below:

FORM-1A

1. The drug (s) or class (es) of drugs intended to be manufactured: -

   (I) Class (es) of drugs
   (II) Dosage form(s) of drugs.
   (III) Name of drug (s).

2. There have been / have not been any change in respect of: -I enclose: -

   i. Name of the proprietor (s) / directors (s)/ partner (s).
   ii. Details of the premises including layout plan of the factory.
   iii. Details of the section-wise equipment and machinery for manufacture and quality control.
   iv. Names and qualifications of the Production In-charge and Quality Control In-charge for supervising manufacturing processes and Quality Control Department, and other technical staff working in these departments.

3. Statement of the Central Research Fund.
   Following statement, as per audited accounts/ based on Income Tax Return for the last five years:-

Year	Investment	Turn-over***	CRF due	C.R.F. ** paid as per Col.4.
1	2	3	4	5

*If there is any change it should be furnished.

**(Original Challan attached).

***Central Research Fund at the rate of 1% of gross profit before deduction of income tax.

(a) Attested copies of the last two income tax assessment order of the Income Tax Department attached.

Dated…… Signed……

Place …… Name Designation & Address……..

ii). Copy of Challan of Fee original duly retained by Statistical Officer DRAP as per following schedule, to be deposited under the following head of account:

A/C No. 0010008463-100018 Allied Bank Limited

1) Fee of Rs. 50,000/- for renewal of DML by way of Formulation.

2) Fee of Rs. 15,000/- for renewal of DML by way of Basic and Semi Basic Formulation.
3) Fee of Rs. 30,000/- for renewal of DML by way of Repacking.
4) Fee of Rs. 5,000/- per Drugs specified in Schedule D for repacking.

iii). All documents submitted should be duly attested.