



Application for Minor Changes in the Allopathic Drug Manufacturing Licence from Food Safety and Drug Administration Department

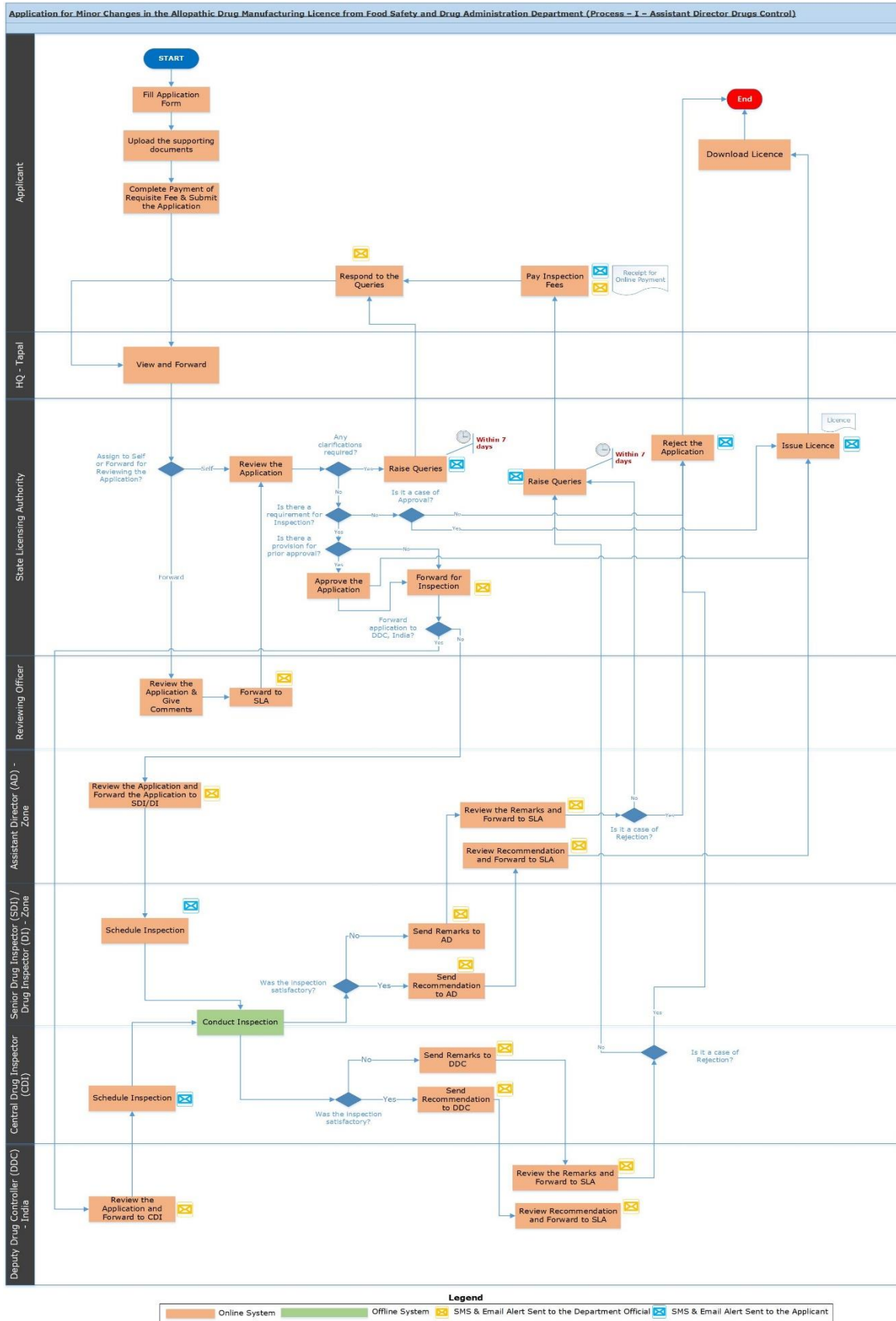
Procedure, List of Supporting Documents and Fees

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1 Procedure

Process I - Application is received by Assistant Director (Zone)



2 Checklist of supporting documents

S. No.	Document
1.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)
2.	Copy of the Drug manufacturing license, if any
3.	Previously issued Form 29 Copy(if any) as specified in the Drugs and Cosmetics Rules, 1945
4.	Document relating to constitution of concerned firm/ Company/ LLP and others. Proprietorship: Declaration Form Partnership Firm: Partnership Deed Limited Liability Partnership: LLP deed, Registration Certificate of ROC Pvt. Ltd. / Ltd: Memorandum and articles of association, Registration Certificate of ROC, Copy of Board resolution Trust: Trust deed Society: Registration Certificate, By Laws, Copy of Resolution passed Hindu Undivided Family: HUF deed
5.	Biodata (with photograph) of the Applicant (s)
6.	Address / ID Proof of the Applicant (s) e. g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card.
7.	Biodata (with photograph) of the Technical Staff (s)
8.	Educational qualification certificate(s) of the Technical Staff (s) (Starting from Minimum Educational Qualification as specified in the Drugs and Cosmetics Rules, 1945)
9.	Experience Certificate of the Technical Staff (s)
10.	Digitally Signed Self-Certification by each Technical Staff stating that He / She is a full-time employee of the Firm under consideration
11.	Address / ID Proof of the Technical Staff (s) e. g. Passport, Driving License, Election Commission ID Card, Aadhaar Card/e-Aadhaar letter downloaded from UIDAI website, Income Tax PAN Card
12.	Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt)
13.	Rental agreement of the premises, if applicable
14.	Plan of the premises- with details of partitions, measurements - Section wise with location of machineries
15.	List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing
16.	List of analytical instruments and equipment for analysis
17.	Purchase invoices with the details like production capacity, make etc. if applicable
18.	Product dossier (for each product)
19.	Form 51/Brand Name affidavit
20.	Agreement with Marketer, if applicable
21.	Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items

3 Fees

INR 500/- per each change.