



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

Procedure, List of Supporting Documents and Fees

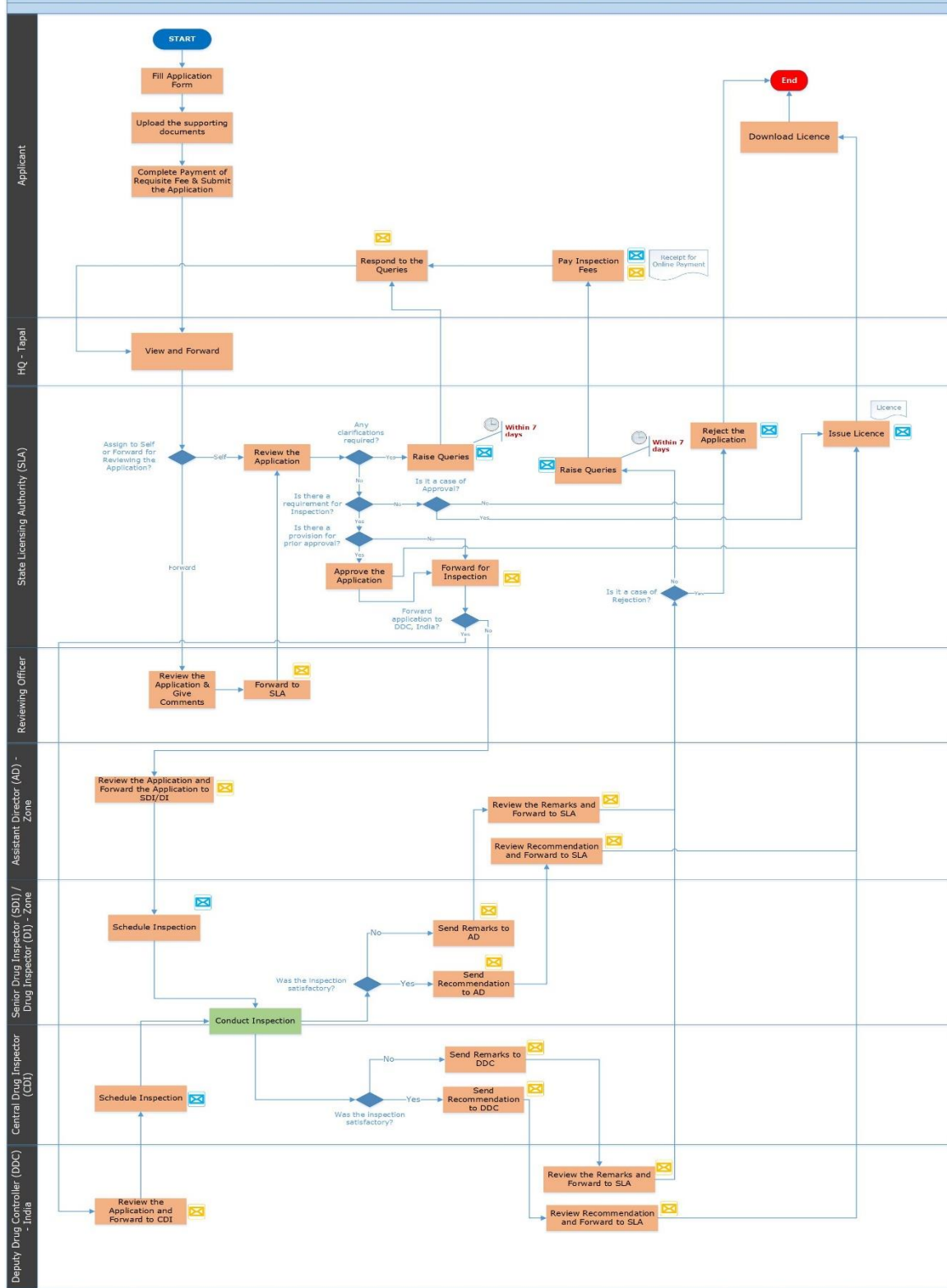
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1 Procedure

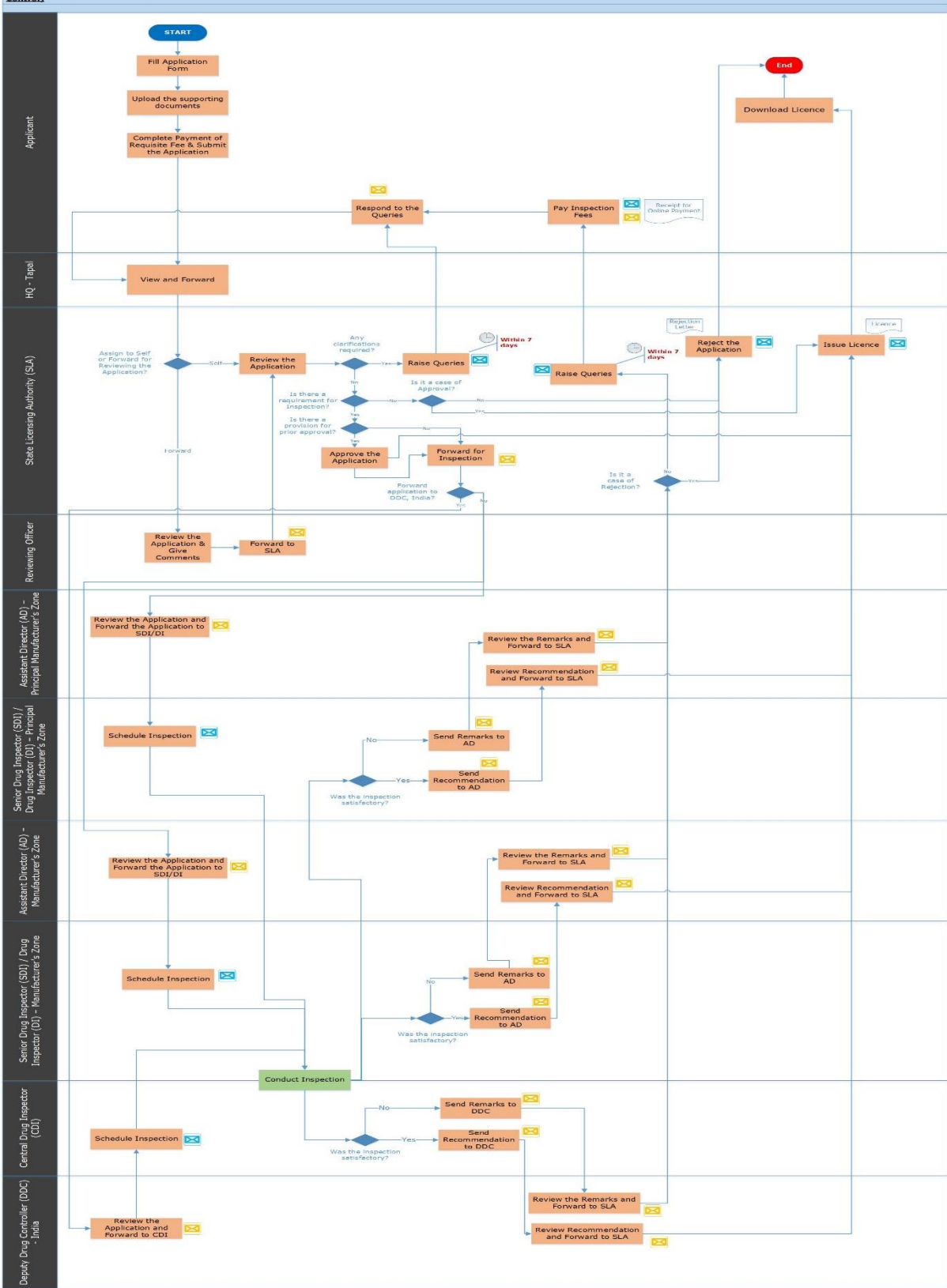
Process I – When the Principal Manufacturer and Manufacturer are in the Same Zone – Application is received by Assistant Director Drugs Control

Application for Minor Changes in the Allopathic Drug Manufacturing Loan Licence from Food Safety and Drug Administration Department (Process – I – Same Zone - Assistant Director of Drugs Control)



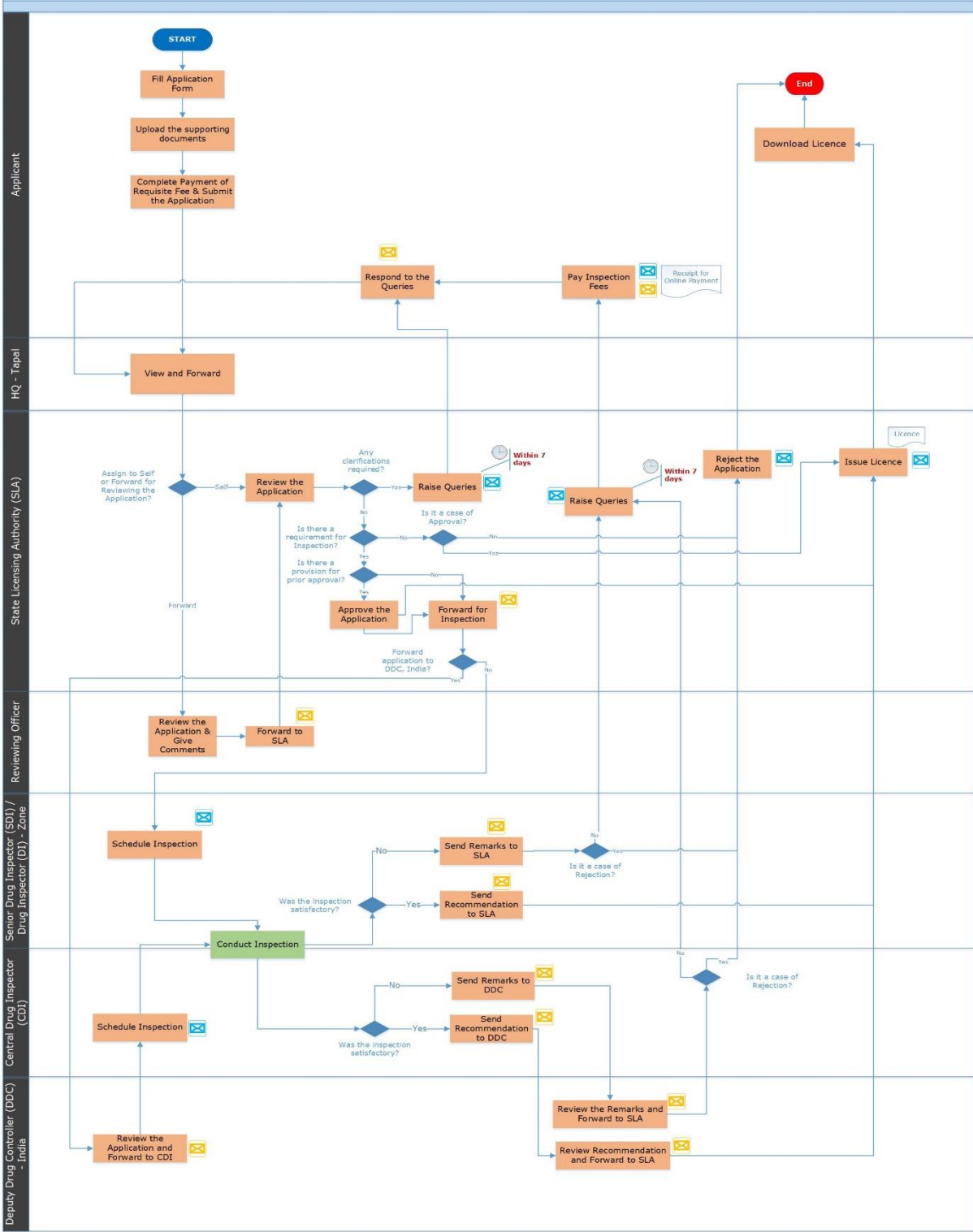
Process II – When the Principal Manufacturer and Manufacturer are in Separate Zones – Application is received by Assistant Director Drugs Control

Application for Minor Changes in the Allopathic Drug Manufacturing Loan Licence from Food Safety and Drug Administration Department (Process – II – Separate Zone - Assistant Director of Drugs Control)



Process III – Application is received by Drug Inspector / Senior Drug Inspector (Head Office)

Application for Minor Changes in the Allopathic Drug Manufacturing Loan Licence from Food Safety and Drug Administration Department (Process – III – Drug Inspector / Senior Drug Inspector)



2 Checklist of supporting documents

S. No.	Document
1.	Covering Letter stating the intent of the application
2.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)
3.	Copy of the Drug manufacturing license, if any
4.	Previously issued Form 29 Copy(if any) as specified in the Drugs and Cosmetics Rules, 1945
5.	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
6.	Biodata (with photograph) of the Applicant (s)
7.	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.
8.	Biodata (with photograph) of the Technical Staff (s)
9.	Educational qualification certificate(s) of the Technical Staff (s) (Starting from Minimum Educational Qualification as specified in the Drugs and Cosmetics Rules, 1945)
10.	Experience Certificate of the Technical Staff (s)
11.	Digitally Signed Self-Certification by each Technical Staff stating that He / She is a full-time employee of the Firm under consideration
12.	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
13.	Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt)
14.	Rental agreement of the premises, if applicable
15.	Plan of the premises- with details of partitions, measurements - section wise with location of machineries
16.	Wholesale Licence Copy
17.	Principal Manufacturer Details (Licenses held by the principal manufacturer along with their product endorsements similar to the proposed one applied by the applicant firm)
18.	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.