Change of Brand Name, Composition, Specification – Allopathic Drug Manufacturing Loan Licence from Food Safety and Drug Administration Department

Procedure, List of Supporting Documents and Fees

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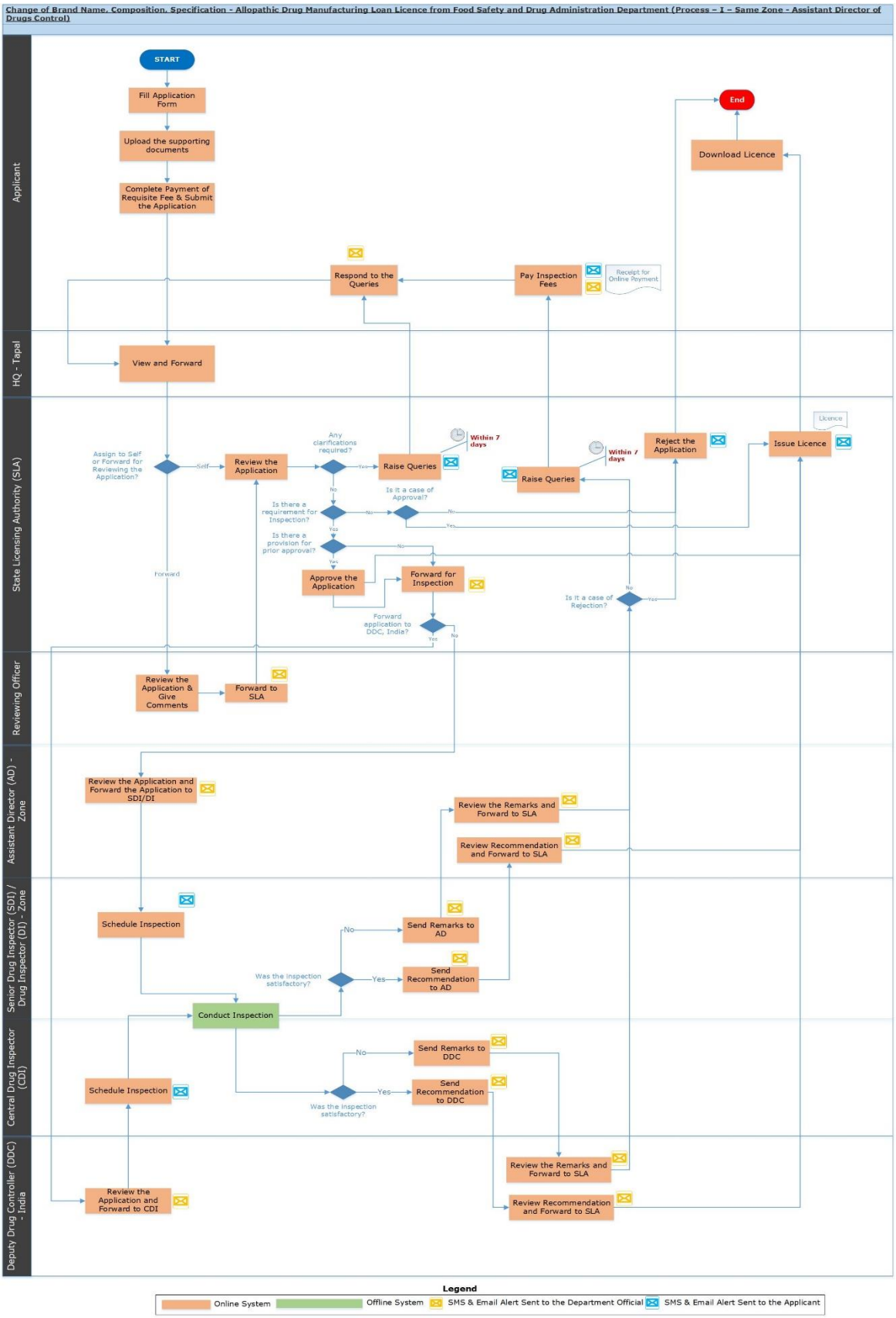
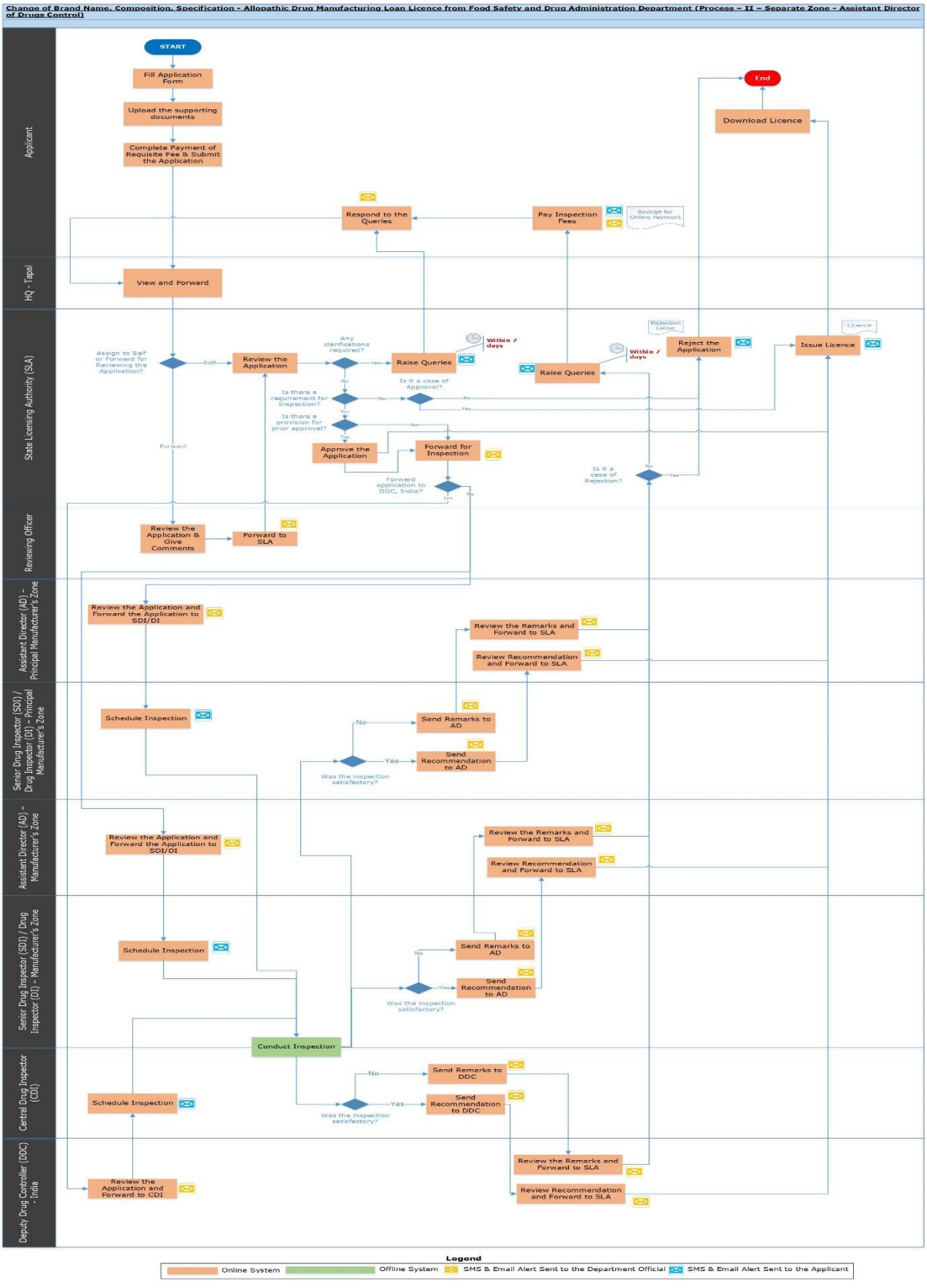
1 Procedure

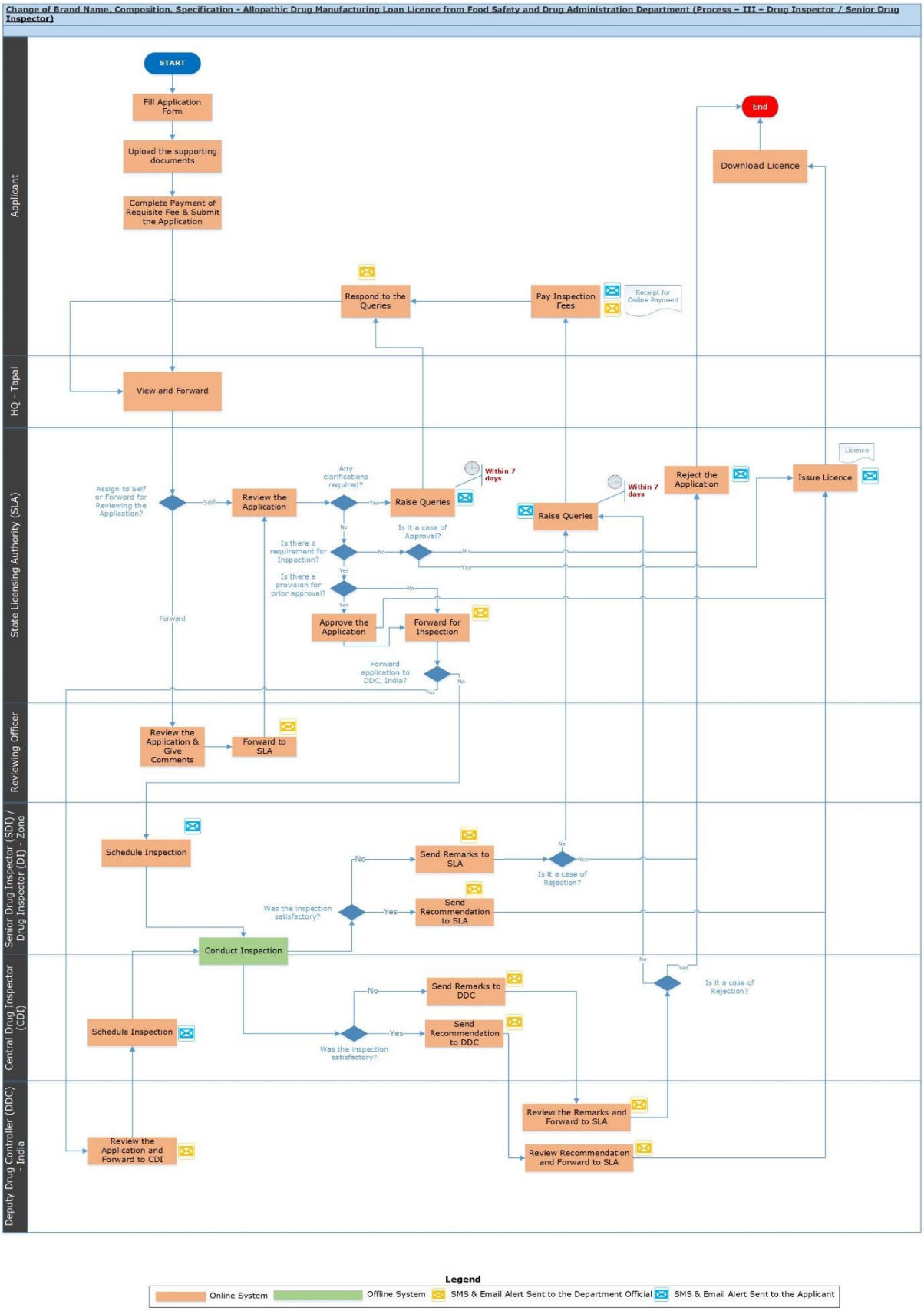
Process I: When the Principal Manufacturer and Manufacturer are in the Same Zone – Application is received by Assistant Director Drugs Control



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



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



Legend

Online System | Offline System | SMS & Email Alert Sent to the Department Official | SMS & Email Alert Sent to the Applicant

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.	Drug manufacturing licences Copy, if any
4.	Previously issued Form 29 Copy, if any
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 fulltime 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, if applicable
17.	Principal Manufacturer Details (Licences 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

S. No.	Fee Type	Fee Per Product for which Change is Proposed (in INR)
1	Form 24A (Drugs other than those specified in Schedule C, C (1) and X of the Drugs and Cosmetics Rules, 1945)	500
2	Form 27A (Schedule C and C (1) excluding those specified in part XB and Schedule X of the Drugs and Cosmetics Rules, 1945)	500

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