Application for Change of Premises – Allopathic Drugs Manufacturing License from Food Safety and Drug Administration Department

Procedure, List of Supporting Documents and Fees

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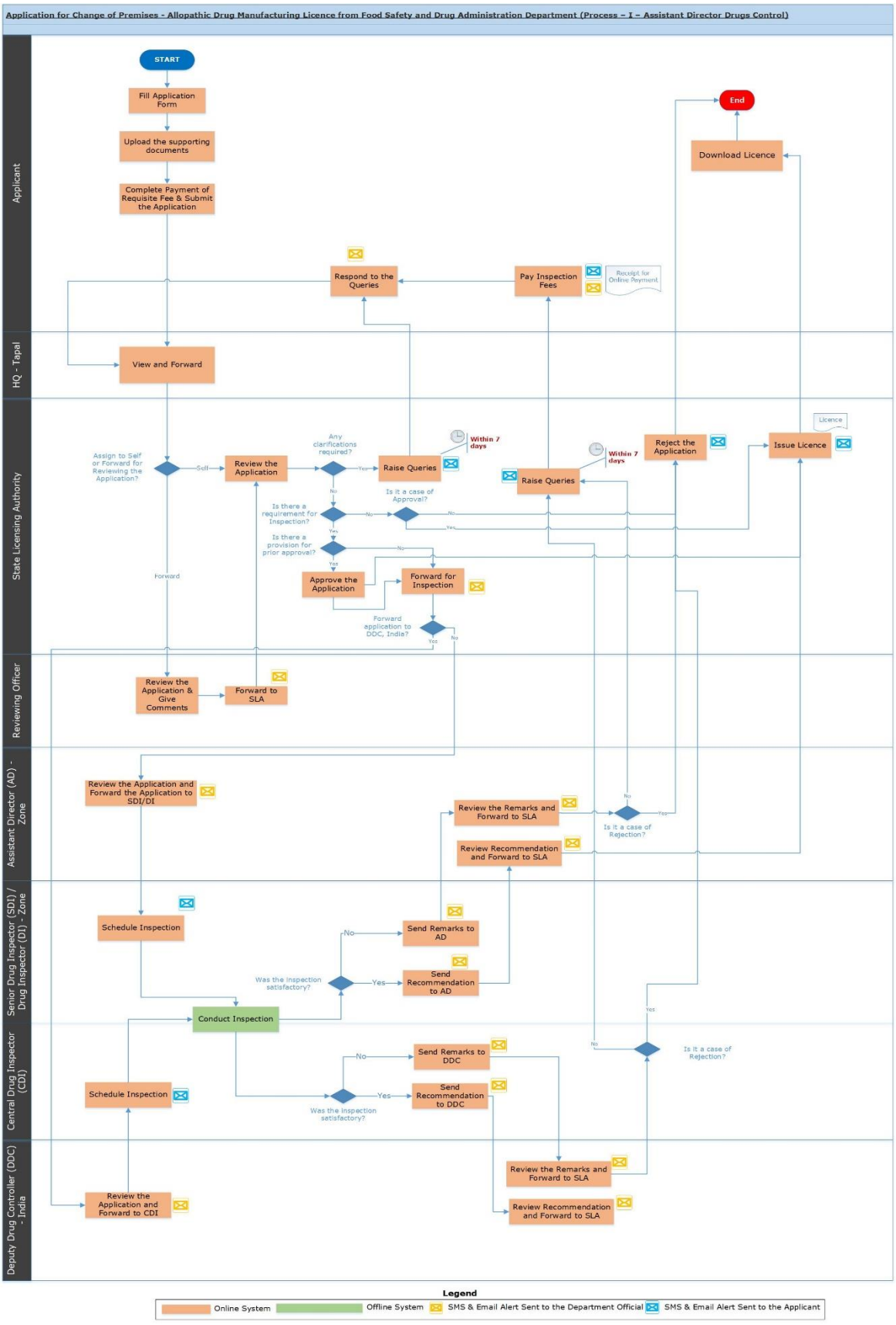
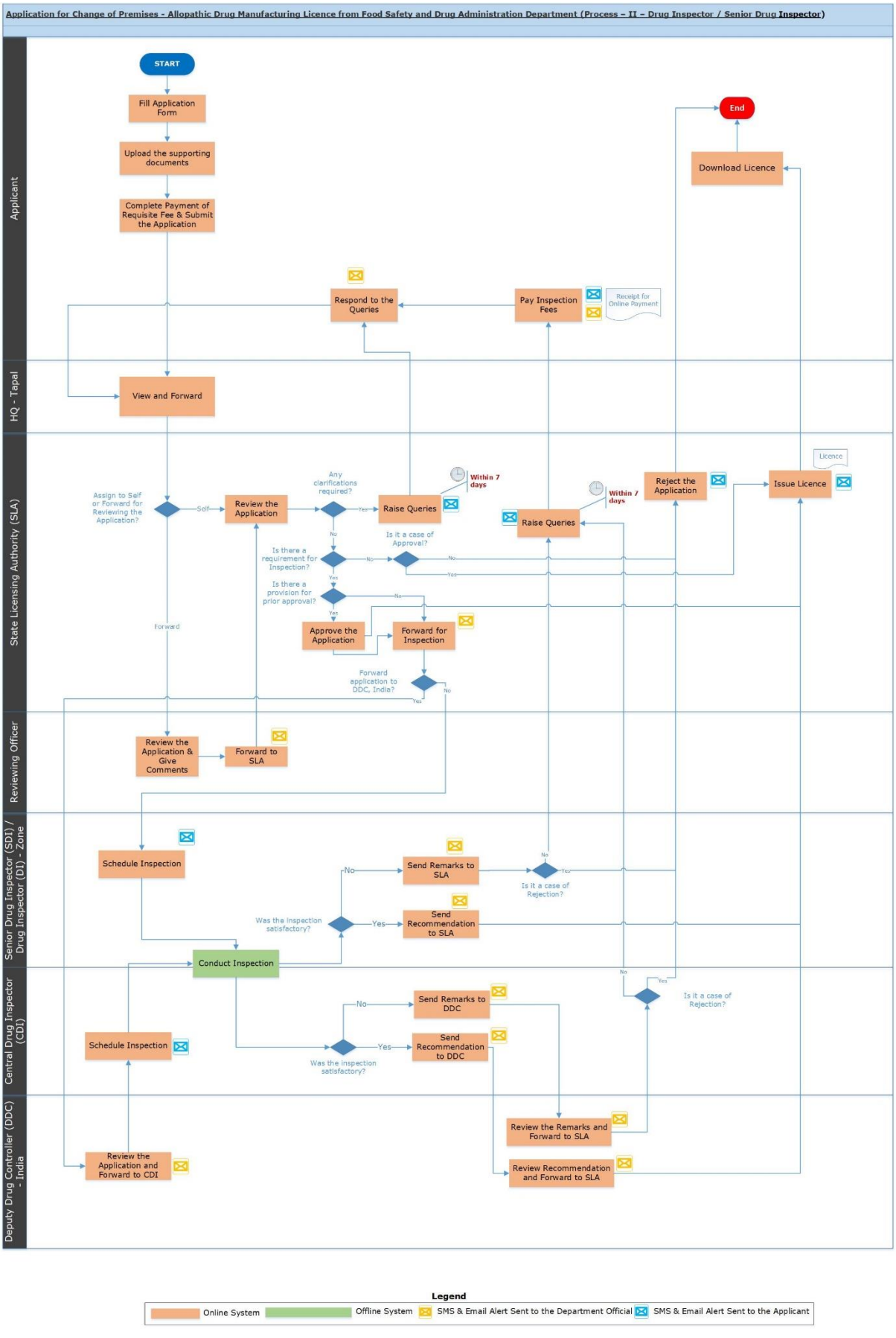
1 Procedure

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



Process II – 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.	Filled Form 24 as specified in the Drugs and Cosmetics Rules, 1945
2.	Filled Form 27 as specified in the Drugs and Cosmetics Rules, 1945
3.	Filled Form 24F as specified in the Drugs and Cosmetics Rules, 1945
4.	Filled Form 27B as specified in the Drugs and Cosmetics Rules, 1945
5.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)
6.	Drug manufacturing licences Copy, if any
7.	Previously issued Form 29 Copy, if any
8.	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
9.	Biodata (with photograph) of the Applicant (s)
10.	Educational qualification certificate(s) of the Technical Staff (s) (Starting from Minimum Educational Qualification as specified in the Drugs and Cosmetics Rules, 1945)
11.	Experience Certificate of the Technical Staff (s)
12.	Digitally Signed Self-Certification by each Technical Staff stating that He / She is a fulltime employee of the Firm under consideration
13.	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
14.	Ownership document of the premises (Registered Sale Deed / Registered General Power of Attorney / Conveyance Deed / Latest Property Tax Receipt)
15.	Rental agreement of the premises, if applicable
16.	Plan of the premises- with details of partitions, measurements - Section wise with location of machineries
17.	List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing
18.	List of analytical instruments and equipment for analysis
19.	Purchase invoices with the details like production capacity, make etc. if applicable
20.	Product dossier (for each product)
21.	Form 51/Brand Name affidavit

S. No.	Document
22.	Agreement with Marketer, if applicable
23.	Any other relevant details or documents to establish the correctness of the details or documents or claims made with regard to the above items

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3 Fees

S. No.	Fee Type	License Fees (INR)	Inspection Fees (INR)	Additional Product Fee for each product after 10 products (in INR)	Total Fees per category
1	Form 24 (Drugs other than those specified in Schedule C, C (1) and X of the Drugs and Cosmetics Rules, 1945)	6,000	1,500	300	7,500 + Addnl. Product Fee
2	Form 27 (Schedule C and C (1) excluding those specified in part XB and Schedule X of the Drugs and Cosmetics Rules, 1945)	6,000	1,500	300	7,500 + Addnl. Product Fee
3	Form 24F (Schedule X and not specified in Schedule C and C (1) of the Drugs and Cosmetics Rules, 1945)	6,000	1,500	300	7,500 + Addnl. Product Fee
4	Form 27B (Specified in Schedules C, C (1) and X of the Drugs and Cosmetics Rules, 1945)	6,000	1,500	300	7,500 + Addnl. Product Fee

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