Issuance of Certificate (with product) not covered under Drugs and Cosmetics Act 1940 by Food Safety and Drug Administration Department

Procedure, List of Supporting Documents and Fees

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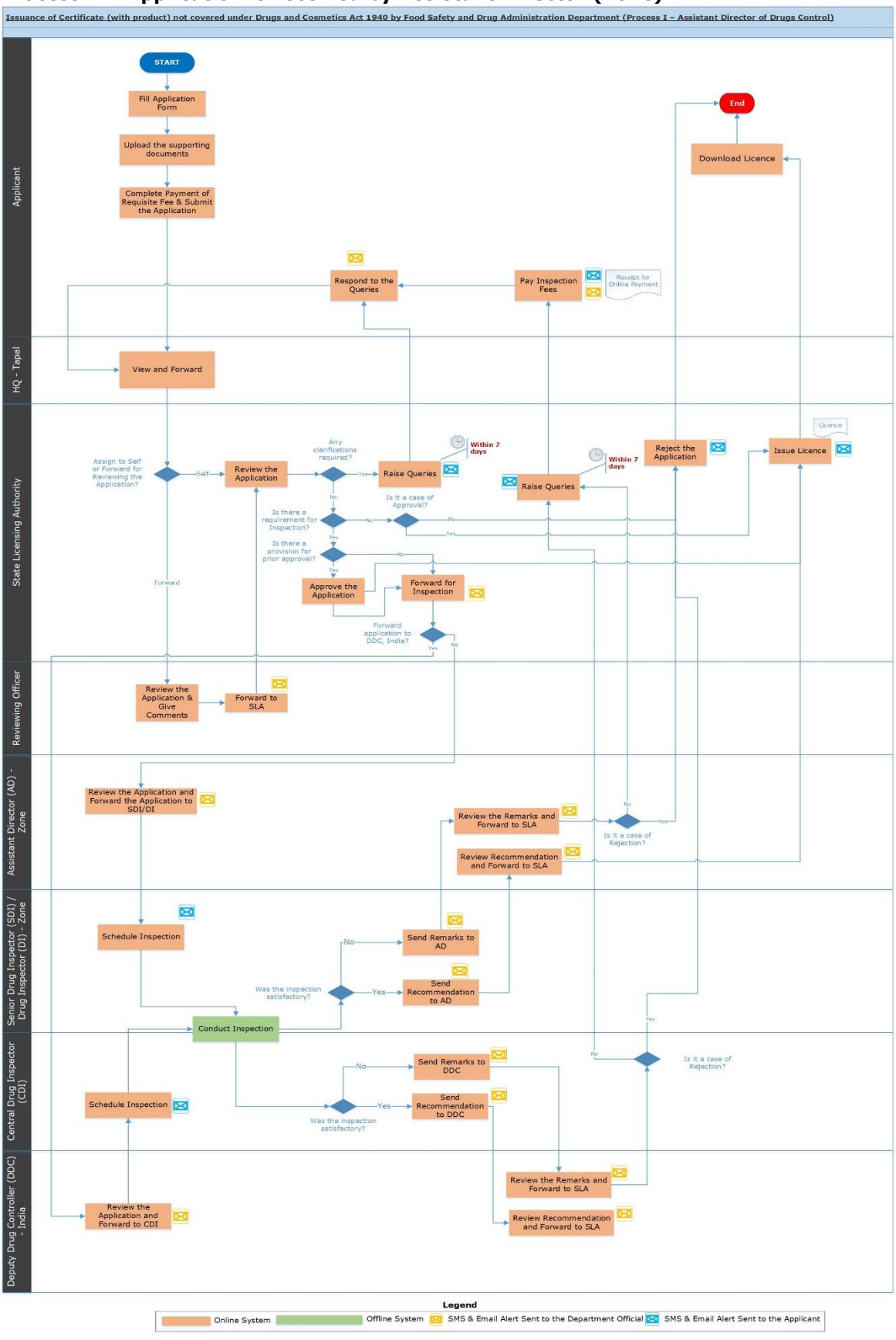
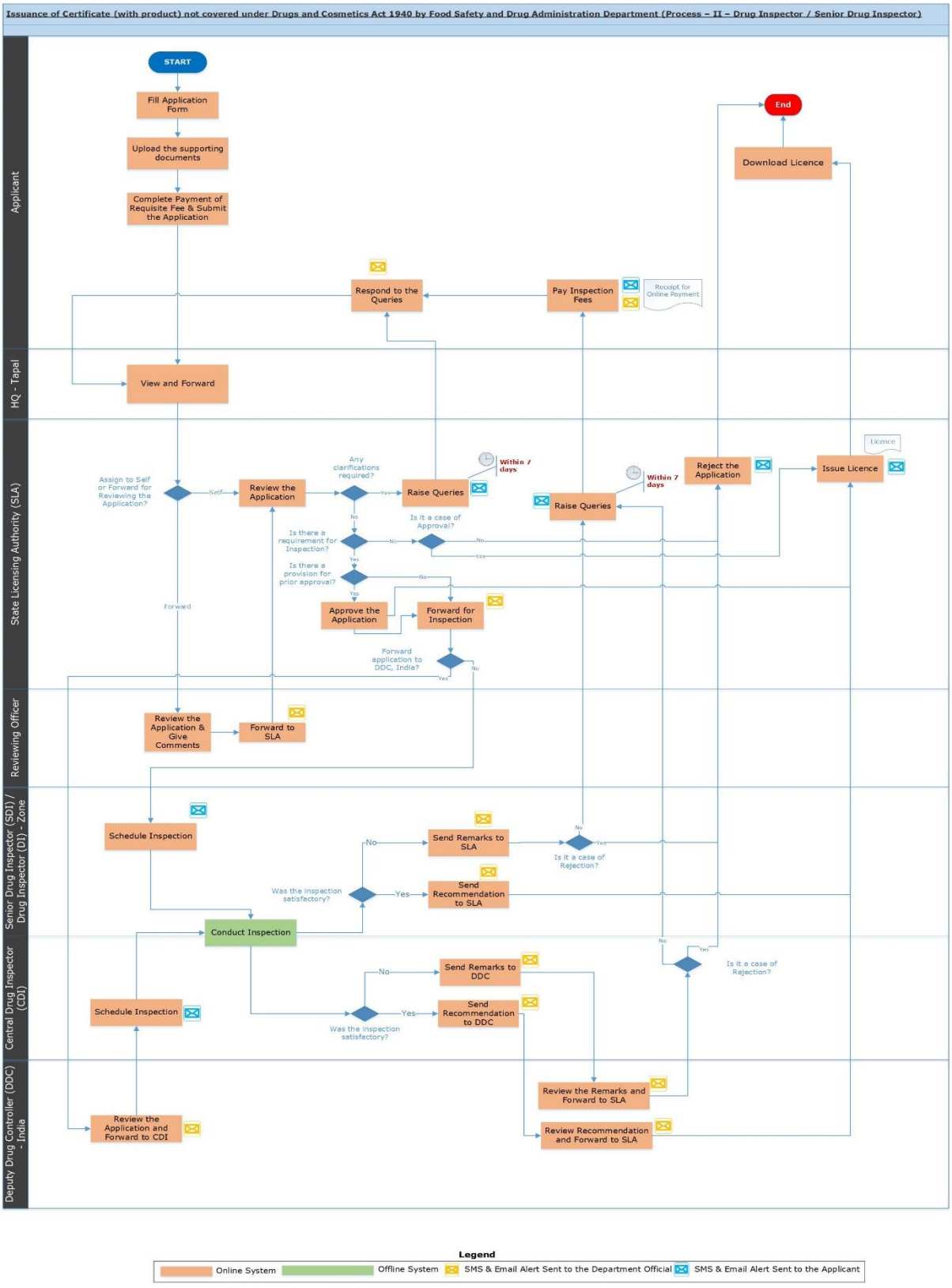
1 Procedure

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



Process II – Application is received by Senior Drug Inspector / Drug Inspector – Head Quarters



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 addressed to the Director of Drugs Control stating the reason for applying for the concerned application
2.	Authorization letter for the signatory of the application form (Board Resolution / Authorisation Letter)
3.	Copy of Licenses/ Renewal Certificate / Retention Fee Receipt / Challans
4.	Scanned copy of WHO GMP Certificate/ Renewal Certificate
5.	Tender Document for which certificate is requested
6.	Previous Certificate (if any)
7.	Annual Turnover Certificate (Audited Profit & Loss Statement)
8.	Sale invoice & Batch Manufacturing Record for each product
9.	Any other documents in support of the application

3 Fees

S. No.	Details	Amount *(in INR per certificate)*
1.	Manufacturing and Market Standing Certificate	300
2.	Non-Cancellation Certificate	300
3.	Performance Certificate	300
4.	Quality & Capacity Certificate	300
5.	Other Certificates	500

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