Additional Product Endorsement – Allopathic Drug Manufacturing Licence from Food Safety and Drug Administration Department

Procedure, List of Supporting Documents and Fees

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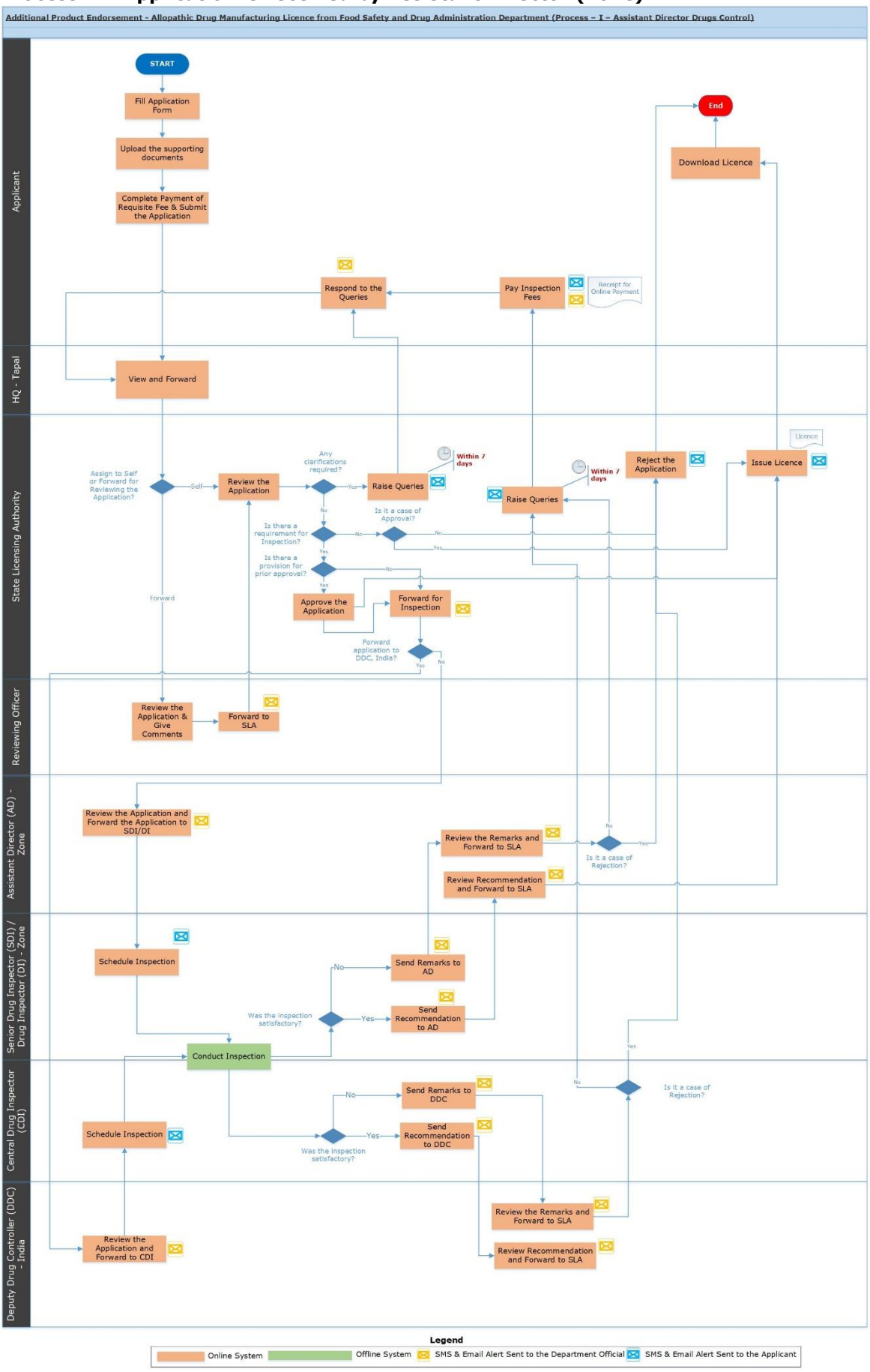
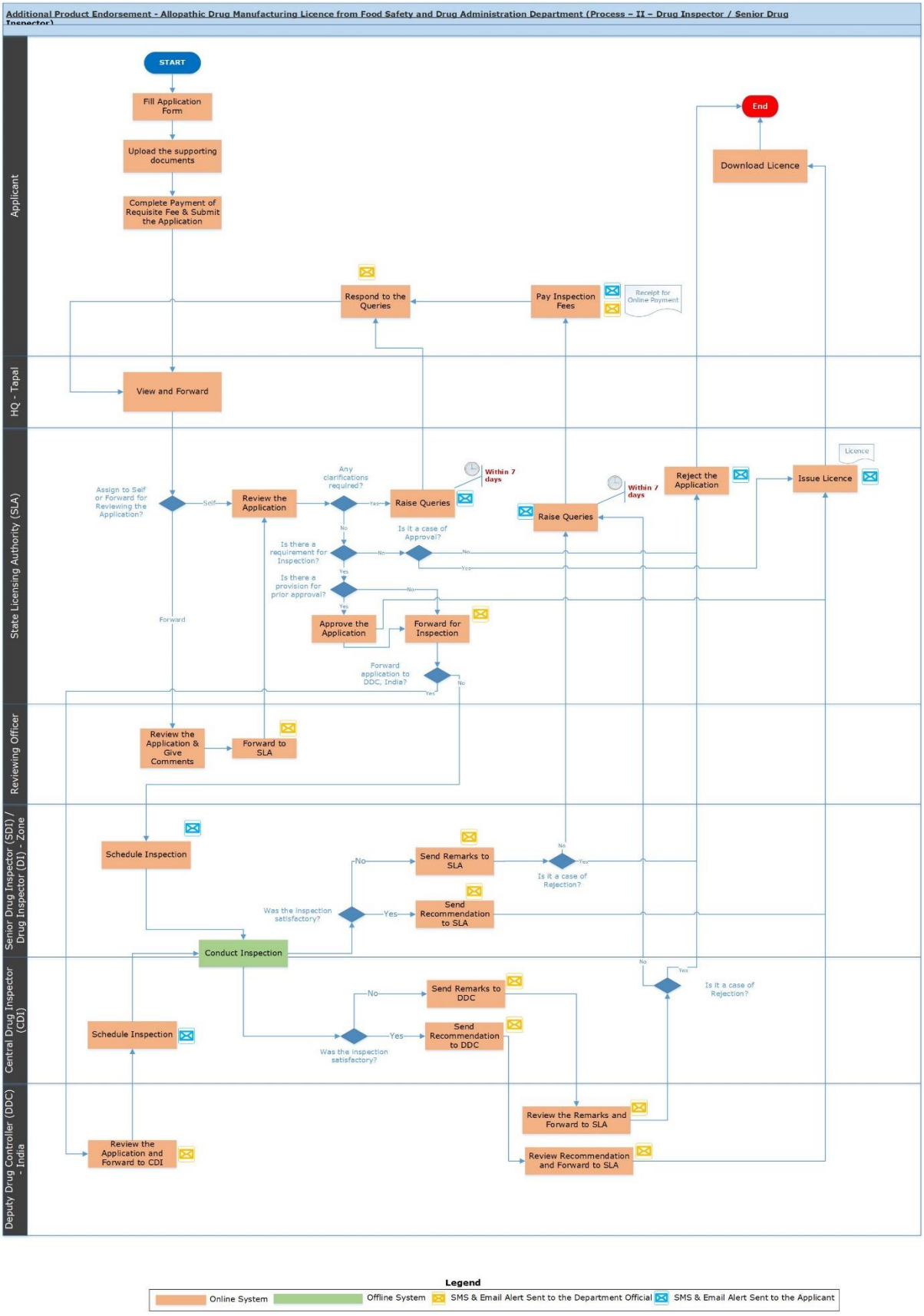
1 Procedure

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



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



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, Latest Renewal certificate / Retention Payment receipt
4.	Previously issued Form 29 Copy, if any
5.	List of machineries and equipment, Air Handling Units, and water system provided Section wise for the manufacturing
6.	List of analytical instruments and equipment for analysis
7.	Copy of purchase invoices with the details like production capacity, make etc. wherever applicable
8.	Product dossier (for each product)
9.	Form 51/Brand Name affidavit
10.	Agreement with Marketer, if applicable
11.	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.	Manufacturing Category	**Inspection Fees (in INR)** *To be charged only if a new category is added*	**Additional Product Fee for each additional Product added (in INR)**
1.	Form 24 (Drugs other than those specified in Schedule C, C (1) and X of the Drugs and Cosmetics Rules, 1945)	1,500	300
2.	Form 27 (Schedule C and C (1) excluding those specified in part XB and Schedule X of the Drugs and Cosmetics Rules, 1945)	1,500	300
3.	Form 24F (Schedule X and not specified in Schedule C and C (1) of the Drugs and Cosmetics Rules, 1945)	1,500	300
4.	Form 27B (Specified in Schedules C, C (1) and X of the Drugs and Cosmetics Rules, 1945)	1,500	300

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