Procedure for renewal of Drug Manufacturing Licences

For renewal certificate of drug manufacturing Licences from this Directorate the applicant should follow procedure given below:

1. For obtaining renewal Licence in Form 26 applicant should fill Form 24/Form 27 along with additional information data. The Forms and the list of all the documents that needs to be submitted may be obtained from the Food & Drugs Administration department or it can also be downloaded from link below.

List of documents to be submitted for Grant of manufacturing Licence

Drug Forms

2. Applicant to pay the necessary fees vide E-challan to be paid to Head of accounts, Demand No. 53; 201 Medical and Public Health, 04 Public Health, 104 Fees and Fines, 01 Fines. Fee structure can also be downloaded from link :
Fee Structure

3. For generation of E- challan applicant needs to fill the challan form available with the department for requisite fees and get it verified from Drugs Inspector and submit it to accounts section where E-challan will be generated and issued to the applicant. Generated E-challan to be paid in the Treasury branch of State Bank of India.

4. Applicant needs to submit all the documents mentioned in the list including original copy of challan paid towards the fees to entry clerk in the inward section.

File movement once it is submitted in entry section is as under:

1. Hard copy of application received in the inward Entry section.
2. Entry clerk forwards the file to Accounts section of the Department for verification of amount paid through challan.
3. The Accounts Section after verification of amount forwards the file to concerned dealing hand.
4. The dealing hand registers the application and scrutinises all the documents and puts up to the Technical Officer.
5. The Technical Officer scrutinises the document submitted and also verifies the product list requested under the said licences; and puts comments and forwards the file to the next supervisory Officer that is either Assistant Drugs Controller (ADC) or the Dy. Director, (Dy. Dir) as the case may be.
6. The ADC or the Dy. Director; reviews the comments / note submitted by the Technical Officer and puts additional comments depending on his/her observations if any and forwards the scrutinised application to the Director; who is the Licensing Authority; with recommendation; depending upon the observation made such as:

a. The deficient documents to be called.
b. Certain clarifications required in the product permission sought.
c. Director (Licensing Authority) on perusal agrees to the recommendations made; and application is sent to the concerned dealing hand.
d. Premises to be inspected to consider Renewal application.

7. Director gives his directions & sends file to dealing hand.
8. In case of recommendations such as a, b, c the concerned dealing hand, puts up a draft of letter conveying the observation and calling up for compliance from the licensee and forwards to the Technical Officer. In case of recommendations at (d) dealing hand puts up the application to the concerned Drugs Inspector for inspection of the premises.
9. In case of recommendations such as a, b, c the Technical Officer forwards the draft to the next superior i.e. the ADC/Dy. Director; who in turn forwards to the Director who approves the draft and send backs to the application file to the concerned dealing hand. In case of observation at d; the Drugs Inspector along with the supervisory officer, ADC/Dy. Director conducts the inspection of the premises for renewal of licences and submit the report to the Director.
10. In case of recommendations such as a, b, c the dealing hand puts up the file with letter communicating the deficiency; to the Technical Officer.
11. The Technical Officer countersigns the same and puts up to the ADC/Dy. Director.
12. The ADC/Dy. Dir. again countersigns and forwards it to the Director for sign.
13. The Director signs the letter and sends the file to Dispatch clerk for dispatch.
14. The Dispatch clerk gives the outward no.; prepare and sends it to the post for delivery.
15. In continuation to step 09; Director peruses the report and then agrees to the recommendation which is either; it is recommended to either.

    (a) Grant the Renewal Certificate; or
    (b) To call for compliance of certain deficiencies.

16. In case of (b) the dealing hand puts up the file with letter communicating the deficiency; to the Drugs Inspector.
17. The Drugs Inspector countersigns the same and puts up to the ADC/Dy. Director.
18. The ADC/Dy. Dir. again countersigns and forwards it to the Director for sign.
19. The Director signs the letter and sends the file to Dispatch clerk for dispatch.
20. The Dispatch clerk gives the outward no.; prepares and sends it to the post for delivery.
21. In continuation to step 15; if grant of renewal of licence is recommended; then the dealing hand puts up the draft of the licence to be issued; along with the covering letter; and the list of products permitted with endorsement; to the Drugs Inspector.
22. The Drugs Inspector verifies the draft for correction and puts up to ADC/Dy. Dir.
23. The ADC/Dy. Dir. Countersigns and puts up to the Director.
24. The Director approves the draft and sends to the dealing hand.
25. The dealing hand prepares the fair renewal certificate along with the list of products and puts up to Drugs Inspector.
26. Steps from 17, 18, 19& 20 are repeated.

27. After compliance of the deficiencies as regards steps 15(b) are submitted by the applicant; dealing hand puts up the file to the concerned Drugs Inspector.
28. The Drugs Inspector verifies the compliance submitted and puts up the noting depending upon the observations made and puts up the file to the ADC/Dy. Dir with recommendation either for grant of licence or for verification of the compliance submitted by visiting the premises.
29. The ADC/Dy. Dir. Puts up their comments and forward the file to DFDA.
30. The DFDA agrees to the recommendations and sends back the file to the dealing hand.
31. The dealing hand depending upon whether it is recommended for grant of licence or for re-inspection; puts up either the draft of the renewal certificate or the file directly to the drugs Inspector.
32. The Drugs Inspector along with ADC/Dy. Dir. Re-inspect the premises and submit their report to the Director with recommendation for grant of licences.
33. Steps from 21 to 25 are repeated.
34. The Drugs Inspector countersigns the renewal certificate and puts up to ADC/Dy. Dir.
35. The ADC/Dy. Dir. Countersigns the renewal certificate and puts up to DFDA for sign.
36. The DFDA signs the licence and sends it to Dispatch clerk for dispatch.

Note: 1) Validity of renewal certificate - valid upto 5 years from issue of renewal certificate subject to the conditions specified in the licence & to the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder.