Procedure for obtaining Manufacturing Drug Licences

Any person who wants to start Manufacturing of drugs should obtain licences from this Directorate under the provisions of Drugs & Cosmetics Act 1940 & Rules thereunder by following the procedure given below.

1. For obtaining Licence in Form 25 (non Biological Drugs) and Form 28 (Biological Drugs) applicant should fill Form 24 and Form 27 respectively 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. Once all the documents are ready the applicant should verify the documents from area Drugs Inspector or any Drugs Inspector of Food & Drugs Administration.

3. After documents are verified and found ok, applicant may 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

4. 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.

5. 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 along with covering letter.

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, generates the file number and scrutinises all the documents and puts up to the Director for alloting to the Drugs Inspector.
5. The Director peruses the application and marks it to any Drugs Inspector/Asst. Drugs Controller for further processes.

6. The Drugs Inspector/ADC of the area scrutinises the documents submitted and also scrutinises the product permission requested under the said licences; and puts comments in the noting.The concerned Drugs Inspector 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.
7. The ADC or the Dy. Director; reviews the comments / note submitted by the Drug Inspector 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 plan of premises submitted.
    c. Certain clarifications required in the product permission sought.
    d. Premises to be inspected to verify whether the facilities provided are in compliance to schedule M, MI, MII, MIII of the Drugs & Cosmetics Rules (as applicable).

8. Director (Licensing Authority) on perusal agrees to the recommendations made; and application is sent to the concerned dealing hand.
9. 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 applicant and forwards to the concerned Drugs Inspectors. In case of recommendations at (d) dealing hand puts up the application to the concerned Drugs Inspector for inspection of the premises.
10. In case of recommendations such as a, b, c the Drugs Inspector forwards the draft to the next superior i.e. the ADC/Director; who in turn forwards it to the Director who approves the draft and sends back 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 manufacturing premises and submits the report to the Director.
11. In case of recommendations such as a, b, c the dealing hand puts up the file with letter communicating the deficiency; to the Drugs Inspector.
12. The Drugs Inspector countersigns the same and puts up to the ADC/Dy. Director.
13. The ADC/Dy. Dir. again countersigns and forwards it to the Director for sign.
14. The Director signs the letter and sends the file to Dispatch clerk for dispatch.
15. The Dispatch clerk gives the outward no.; prepares and sends it to the post for delivery.
16. In continuation to step 10; Director peruses the report and then agrees to the recommendation which is either; it is recommended to either

    (a) Grant the licence; or

    (b) To call for compliance of certain deficiencies.

17. In case of (b) the process from step no. 9 to 15 is repeated.
18. In continuation to step 16; if grant 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.
19. The Drugs Inspector verifies the draft for correction and puts up to ADC/Dy. Dir.
20. The ADC/Dy. Dir. Countersigns and puts up to the Director.
21. The Director approves the draft and sends to the dealing hand.
22. The dealing hand prepares the fair licence along with the list of products and puts up to Drugs Inspector.
23. Steps from 12, 13, 14 and 15 are repeated.
24. After compliance of the deficiencies as regards steps 16(b) are submitted by the applicant; dealing hand puts up the file to the concerned Drugs Inspector.
25. 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.
26. The ADC/Dy. Dir. Puts up their comments and forwards the file to DFDA.
27. The DFDA agrees to the recommendations and sends back the file to the dealing hand.
28. The dealing hand depending upon whether it is recommended for grant of licence or for re-inspection; puts up either the draft of the licence or the file directly to the Drugs Inspector.
29. 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.
30. Steps from 18 to 22 are repeated.
31. The Drugs Inspector countersigns the licence and puts up to ADC/Dy. Dir.
32. The ADC/Dy. Dir. Countersigns the licence and puts up to DFDA for sign.
33. The DFDA signs the licence and sends it to Dispatch clerk for dispatch.

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

2) Click on the link below for timelines:

Citizen charter