CIRCULAR

No. DCD/D&D/LA/2017-2018/ 198 **Dated: -06/10/2017.**

Sub: - Information about the time-lines to clear the application, comprehensive list of documents required and procedure of department for granting and renewal of Drugs Manufacturing Licence.

1) Time-line to clear application for granting and renewal of Drugs Manufacturing Licence.

28 DAYS

2) Procedure and list of documents to clear the application for granting and renewal of Drugs Manufacturing Licence.

<table>
<tr><td>Step -1</td><td>The Applicant will apply for the approval of Plant Lay-out along with the following documents before the grant of fresh manufacturing licence.

List of Documents.

<table>
<tr><th>Sr. No.</th><th>Documents</th><th>No. of copies</th></tr>
<tr><td>1</td><td>Covering letter</td><td>1 copy</td></tr>
<tr><td>2</td><td>Self Assesed check list of documents</td><td>1 copy</td></tr>
<tr><td>3</td><td>List of Directors with address</td><td>1 copy</td></tr>
<tr><td>4</td><td>Copy of Power of attorney to sign the documents.</td><td>1 copy</td></tr>
<tr><td>5</td><td>Copy of Plan approval</td><td>1 copy</td></tr>
<tr><td>6</td><td>Noc/Consent from SSI, Pollution.</td><td>1 copy</td></tr>
<tr><td>7</td><td>Copy of Memorandum of Articles</td><td>1 copy</td></tr>
</table></td></tr>
<tr><td>Step -2</td><td>The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.</td></tr>
<tr><td>Step -3</td><td>The Drugs Inspector will examine the attached documents and study the plant lay-out as per the guidelines of Schedule –M of the Drugs & Cosmetics Rules, 1945. And if any deficiency in documents or any observations then will convey to the applicant for necessary rectification.</td></tr>
<tr><td>Step -4</td><td>After the compliance of observations of Drugs Inspector, the application will be forwarded to the Drugs Licensing Authority for approval.</td></tr>
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<table>
<tr><td>Step - 5</td><td>The Drugs Licensing Authority after the compliance will issue /approve the Plant Lay-out with his/her signature.</td></tr>
<tr><td>Step – 6</td><td>After the approval of Plant Lay-out the applicant with following documents and necessary application fee will apply for the grant/renewal of Drugs Manufacturing Licence.
<table>
<tr><th>Sr. No.</th><th>Documents</th><th>No. of copies</th></tr>
<tr><td>1</td><td>Covering letter alongwith payment of application fee.</td><td>1 copy</td></tr>
<tr><td>2</td><td>Self Assesed check list of documents</td><td>1 copy</td></tr>
<tr><td>3</td><td>Form 24 & 27 (Maximum 10 Products should apply under each form)</td><td>1 copy</td></tr>
<tr><td>4</td><td>Product List.</td><td>2 copies</td></tr>
<tr><td>5</td><td>List of Excipients.</td><td>1 copy</td></tr>
<tr><td>6</td><td>Similar Product.</td><td>1 copy</td></tr>
<tr><td>7</td><td>Draft Label.</td><td>1 copy</td></tr>
<tr><td>8</td><td>Method of Analysis.</td><td>1 copy</td></tr>
<tr><td>9</td><td>Additional Information Form.</td><td>1 copy</td></tr>
<tr><td>10</td><td>Copy of Memorandum of Articles</td><td>1 copy</td></tr>
<tr><td>11</td><td>List of Directors with address</td><td>1 copy</td></tr>
<tr><td>12</td><td>Copy of Power of attorney to sign the documents.</td><td>1 copy</td></tr>
<tr><td>13</td><td>Copy of Plan approval</td><td>1 copy</td></tr>
<tr><td>14</td><td>Noc/Consent from SSI, Pollution.</td><td>1 copy</td></tr>
</table></td></tr>
<tr><td>Step - 7</td><td>The designated /Inward clerk will accept the application and will forward to the Drugs Inspector.</td></tr>
<tr><td>Step - 8</td><td>The Drugs Inspector will Scrutiny the application and will inspect factory premises.</td></tr>
<tr><td>Step – 9</td><td>The Drugs Inspector will convey to the applicant, if any deficiencies in documents and observation of inspection.</td></tr>
<tr><td>Step –10</td><td>After the compliance of observations the Drugs Inspector will forward the application to Drugs Licensing Authority.</td></tr>
<tr><td>Step -11</td><td>After the Compliance the Drugs Licensing Authority will grant the licence with his/her signature.</td></tr>
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(Dr. Dharmesh Agrawal)
Drugs Licensing Authority,
UT of Daman & Diu,
Daman.