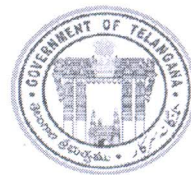




DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.12902/E(G)/TS/2016

Dated: 27-04-2017.

To

M/s.Divis Pharmaceuticals (P) Ltd
Sy.No.10, Gaddapotharam Village
Kazipally Indl. Estate, Jinnaram Mandal
Medak District, Telangana State, India.

Sirs,

Sub: Drugs and Cosmetic Act.1940 and Rules made thereunder -
Renewal of Drug Licence in Form-25 for the period 01.01.2017 to
31.12.2021 - Regarding.

Ref: Your application dated: 14.12.2016

-X-X-X-

With reference to your application cited, I forward herewith the Drug Licence bearing No.211/MD/AP/96/B/R, dated:05.12.1994 in Form-25 duly renewed for the period from 01-01-2017 to 31-12-2021 for the manufacture of products as mentioned below:

LIST OF PRODUCTS IN FORM-25

- | | | |
|---|------------------|----------------------------|
| 1. Fluoxetine HCL | IP/BP/Ph.Eur/USP | (BP/Ph.Eur/USP for Export) |
| 2. Ketorolac Tromethamine | IP/USP | (USP for Export) |
| 3. Ketorolac Tromethamol | BP/Ph.Eur | (For Export) |
| 4. Oxymetazoline HCL | USP/BP/Ph.Eur | (Domestic & Export) |
| 5. Xylometazoline HCL | USP/Ph.Eur/BP/IP | (USP/Ph.Eur/BP for export) |
| 6. Clopidogreal Bisulphate | USP/IP | (USP for Export) |
| 7. Clopidogril Hydrogen Sulphate Ph.Eur | | (For Export) |
| 8. Fenofibrate | USP/Ph.Eur/IP | (USP/Ph.Eur for export) |
| 9. Pregabalin | IP | (Domestic & Export) |
| 10.Bupropion | USP | (Domestic & Export) |
| 11.Atomoxetin Hydrochloride | USP/Ph.Eur/IP | (USP/Ph.Eur for Export) |

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21.4.2017



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.12902/E(G)/TS/2016, Renewal of M/s. Divis Pharmaceuticals (P) Ltd, Sy.No.10, Gaddapotharam Village, Kazipally Indl. Estate, Jinnaram Mandal, Medak District, Telangana State, India under drug manufacturing licence bearing No. 211/MD/AP/96/B/R, dated:05.12.1994 in Form-25 duly renewed for the period from 01-01-2017 to 31-12-2021.

Further, the Drug Licence is renewed, subject to the following conditions.

- 1) You are informed that on failure to manufacture the items approved herewith without a reasonable cause during the licensing period the matter will be reviewed and the items are liable for deletion.
- 2) The provision of Drugs price Control Order, 2013 shall be complied with.
- 3) You should note that the brand names approved herewith are without prejudice to the existing brand names and are liable for review in future, if necessary.
- 4) You should ensure that the items approved herewith shall not make any false/misleading/ objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour, combination etc., and shall comply with all the provisions relating to the labeling of drugs.

- 5) Specific permission for each export order need not be obtained. However, the details of exports by the exporter shall be furnished immediately after completion of each export in the format mentioned below.

Sl.	Date of export.	Names of the drugs exported	Batch No. of the drug.	Quantity of the drug.	Name of importing country.	No.
1.	2.	3.	4.	5.	6.	

- 6) Detailed particulars of rejects/ returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/disposed of in any other manner.
- 7).The specification/standards asked for by the Importing Country/firm shall be complied with while exporting the drugs.
- 8).The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs.

In case of Narcotics/Psychotropic Drugs, you are also directed to approach the Narcotic Commissioner of India, 19th The Mal Morar, Gwalior-6 so far as the provisions of the NDPS Act and the Rules are concerned in the matter.



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21.4.2017

Pg 2 of 3

M. AMRUTH RAO, M. Pharm, L.L.M.,
Joint Director (ENF)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad-500 038.



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.12902/E(G)/TS/2016, Renewal of M/s. Divis Pharmaceuticals (P) Ltd, Sy.No.10, Gaddapotharam Village, Kazipally Indl. Estate, Jinnaram Mandal, Medak District, Telangana State, India under drug manufacturing licence bearing No. 211/MD/AP/96/B/R, dated:05.12.1994 in Form-25 duly renewed for the period from 01-01-2017 to 31-12-2021.

Further, you are informed that non-compliance of any of the conditions mentioned above the matter will be reviewed and the licences /permission issued herewith are liable for suspension /cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetic Rules. You are therefore requested to plan your production accordingly.



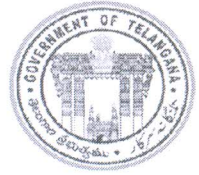
Yours faithfully

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21-4.2017

M.AMRUTH RAO
Joint Director & Licensing Authority



DRUGS CONTROL ADMINISTRATION
Government of Telangana



RENEWAL OF DRUG LICENCE IN FORM-25

FORM – 26

[See Rule 73 and 83]

Certificate of renewal of licence to manufacture for sale of drugs other than those specified in Schedule X

1. Certified that licence No.**211/MD/AP/96/B/R**, granted on the 05.12.1994 to M/s.**Divis Pharmaceuticals Pvt, Ltd**, for the manufacture of the following categories of drugs being drugs other than those specified in Schedules C and C(1) and X drugs specified in Schedules C and C(1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945 at the premises situated at Sy.No.10, Gaddapotharam Village, Kazipally Indl.Estate, Jinnaram Mandal, Medak District, Telangana State, India has been renewed from **01-01-2017 to 31-12-2021**.

2. Names of Approved Competent Technical Staff

- | | |
|--------------------------------|---|
| 1.Mr.N.V.Nageaswara Rao, M.Sc- | Analytical Chemist |
| 2.Mr.K.Srinivasa Rao, B.Sc | - Analytical chemist for Chemical and Instrumental Analysis |
| 3.Mr.J.Nagaraju, M.Sc | - Manufacturing Chemist |
| 4.Mr.N.Verra Babu, B.Sc | - Manufacturing Chemist |
| 5.Mr.N.Surya Naga Raju, B.Sc | - Manufacturing Chemist |
| 6.Mr.G.Veera Raju, B.Sc | - Manufacturing Chemist |

3. Names of the drugs

List enclosed

Date: 29 .04.2017



Signature.....

Designation.....

Licensing Authority.....

M. AMRUTH RAO, M. Pharm, L.L.M.,
Joint Director (ENF)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad-500 038.