F. No. J-11011/7/2013- IA II (I)  
Government of India  
Ministry of Environment and Forests  
(I.A. Division)  
Paryavaran Bhawan  
CGO Complex, Lodhi Road  
New Delhi – 110 003  
E-mail : vp.upadhyay@nic.in  
Telefax : 011: 2436 2875  
Dated 29th April, 2013  

To,  
Shri P. Nageswara Rao (Managing Director)  
M/s SVR Laboratories Pvt. Ltd.  
H.No. 7-1-307/14/F/52, Jayaprakash Nagar,  
Sanathnagar, Hyderabad 500 018  

E-mail: teamlabs@gmail.com ; svrlaboratories@yahoo.co.in ; Fax No.: 040-23712445  

Subject: Expansion of Synthetic Organic Chemicals Manufacturing Unit at Village Dothigudem, Mandal Pochampally, District Nalgonda, Andhra Pradesh by M/s SVR Laboratories Pvt. Ltd. -regarding TORs  


Sir,  

Kindly refer your letter no. nil dated 5th December, 2012 alongwith project documents including Form-I, Pre-feasibility Report and draft ‘Terms of Reference’ as per the EIA Notification, 2006. It is noted that proposal is for expansion of Synthetic Organic Chemicals Manufacturing Unit at Village Dothigudem, Mandal Pochampally, District Nalgonda, Andhra Pradesh by M/s SVR Laboratories Pvt. Ltd. Following is the details of existing and proposed products:

<table>
<thead>
<tr>
<th>Name of the Product (Existing)</th>
<th>Capacity (Kg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 hydroxy carbonole (Intermediate for stage -1 intermediate of carvidilol)</td>
<td>16.67</td>
</tr>
<tr>
<td>2(2,4 Difluorophenyl)-1-(1H-1,2,4)-Trizole-1-YL)-2,3 epoxy-propane methane) sulfonate(state 2 intermediate of Fluconazole)</td>
<td>16.67</td>
</tr>
<tr>
<td>Total</td>
<td>33.34</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Name of the Product (Proposed)</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Kg/Day</td>
</tr>
<tr>
<td>I.Bulk drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Acyclovir</td>
<td>130</td>
</tr>
<tr>
<td>2</td>
<td>Atorvatin Calcium</td>
<td>150</td>
</tr>
<tr>
<td>3</td>
<td>Capecitabine</td>
<td>50</td>
</tr>
<tr>
<td>4</td>
<td>CBZ-L-Valine</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>Cevimeline Hydrochloride</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Drug Name</td>
<td>Quantity</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>6</td>
<td>Clofarabine</td>
<td>40</td>
</tr>
<tr>
<td>7</td>
<td>Eprsartan mesylate</td>
<td>50</td>
</tr>
<tr>
<td>8</td>
<td>Felbamate</td>
<td>160</td>
</tr>
<tr>
<td>9</td>
<td>Gemcitabine Hydrochloride</td>
<td>100</td>
</tr>
<tr>
<td>10</td>
<td>Levofloxacinc</td>
<td>60</td>
</tr>
<tr>
<td>11</td>
<td>Lopinavir</td>
<td>125</td>
</tr>
<tr>
<td>12</td>
<td>Losartan Potassium</td>
<td>300</td>
</tr>
<tr>
<td>13</td>
<td>Methyl 1,2,4-tri-O-cetyl-3-O-benzyl-L-idopyranuronate</td>
<td>40</td>
</tr>
<tr>
<td>14</td>
<td>Methyl 2,3-di-O-benzyl-4-O-chloro acetyl- b-D-glucopyranuronate</td>
<td>50</td>
</tr>
<tr>
<td>15</td>
<td>Methyl 6- O-acetyl-3-O-benzyl-2-(benzyl oxyarbonyl)amino - 2- deoxy-a - D-glucopyranoside</td>
<td>180</td>
</tr>
<tr>
<td>16</td>
<td>Moxifloxacinc Hydrochloride</td>
<td>70</td>
</tr>
<tr>
<td>17</td>
<td>Pantoprazole Sodium</td>
<td>333.33</td>
</tr>
<tr>
<td>18</td>
<td>Pregabalin</td>
<td>300</td>
</tr>
<tr>
<td>19</td>
<td>Ritonavir</td>
<td>100</td>
</tr>
<tr>
<td>20</td>
<td>Rizatriptan</td>
<td>70</td>
</tr>
<tr>
<td>21</td>
<td>Rosuvastatin Clacium</td>
<td>100</td>
</tr>
<tr>
<td>22</td>
<td>Saxagliptin monohydrate</td>
<td>70</td>
</tr>
<tr>
<td>23</td>
<td>Tenofovir Disoproxil</td>
<td>100</td>
</tr>
<tr>
<td>24</td>
<td>Valacyclovir Hydrochloride</td>
<td>180</td>
</tr>
<tr>
<td>25</td>
<td>Valsartan</td>
<td>130</td>
</tr>
<tr>
<td>26</td>
<td>Zileuton</td>
<td>100</td>
</tr>
<tr>
<td>27</td>
<td>1,6-anhydro-2-azido-2-deoxy-b-D-glucopyranuronate</td>
<td>50</td>
</tr>
<tr>
<td>28</td>
<td>3-O-acetyl-1,6-anhydro-2-azido-2-deoxy-D-glucopyranuronate</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td><strong>Total - I - Worst Case (Any 8 products on campaign basis.)</strong></td>
<td><strong>1733.33</strong></td>
</tr>
</tbody>
</table>

**II. Intermediates**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(   )-3-(Carbamoylmethyl)-5-methyl hexanoic acid</td>
<td>100</td>
<td>3000</td>
</tr>
<tr>
<td>2</td>
<td>2- chloromethyl-3,4-dimethoxy pyridine Hydrochloride(Pantoprazole Chloro compound)</td>
<td>333.33</td>
<td>10000</td>
</tr>
<tr>
<td></td>
<td><strong>Total - II</strong></td>
<td><strong>433.33</strong></td>
<td><strong>13000</strong></td>
</tr>
</tbody>
</table>

**Grand Total (I + II)**  
2167.66  
65000  

2.0 Draft Terms of Reference (TOR) have been discussed and finalized during the 6th Reconstituted Expert Appraisal Committee (Industry) held during 5th March, 2013-7th March, 2013 for preparation of EIA/EMP report. Following are the 'TORs':
1. A separate chapter on status of compliance of Environmental Conditions granted by State/Centre to be provided. As per circular dated 30th May, 2012 issued by MoEF, a certified report by RO, MoEF on status of compliance of conditions on existing unit to be provided in EIA/EMP report.
2. Executive summary of the project
3. Justification of the project
4. Promoters and their background
5. Regulatory framework
6. Environment clearance for the existing unit issued by the Ministry (reasons, if not obtained), Consent to Operate and Authorization accorded by the APPCB.
7. Data for the stack emissions, fugitive emissions; water requirement and water balance chart; wastewater generation, treated effluent quality, re-utilization and disposal of solid/hazardous waste for the existing unit.
8. Project location and plant layout.
9. Infrastructure facilities including power sources.
10. Total cost of the project alongwith total capital cost and recurring cost/annum for environmental pollution control measures.
11. Project site location alongwith site map of 10 km area and site details providing various industries, surface water bodies, forests etc.
12. Present land use based on satellite imagery for the study area of 10 km radius. Details of land availability for the project alongwith supporting document.
13. Location of National Park/Wild life sanctuary/Reserve forest within 10 km radius of the project.
14. Permission from the State Forest Department regarding the impact of the proposed plant on the surrounding reserve forests.
15. Details of the total land and break-up of the land use for green belt and other uses.
16. List of products alongwith the production capacities.
17. Detailed list of raw material required and source, mode of storage.
18. Manufacturing process details alongwith the chemical reactions and process flow chart.
19. Action plan for the transportation of raw material and products.
20. Site-specific micro-meteorological data using temperature, relative humidity, hourly wind speed and direction and rainfall is necessary.
21. Ambient air quality monitoring at 6 locations within the study area of 5 km., aerial coverage from project site as per NAAQS notified on 16th September, 2009. Location of one AAQMS in downwind direction.
22. One season site-specific micro-meteorological data using temperature, relative humidity, hourly wind speed and direction and rainfall and AAQ data (except monsoon) for PM$_{10}$, SO$_2$, NOx, CO including VOCs shall be collected. The monitoring stations shall take into account the pre-dominant wind direction, population zone and sensitive receptors including reserved forests. Data for water and noise monitoring shall also be included.
23. Air pollution control measures proposed for the effective control of gaseous/process emissions within permissible limits.
24. Name of all the solvents to be used in the process and details of solvent recovery system.
25. Design details of ETP, incinerator, if any alongwith boiler, scrubbers/bag filters etc.
26. Details of water and air pollution and its mitigation plan.
27. Action plan to control ambient air quality as per NAAQS Standards notified by the Ministry on 16th September, 2009.
28. An action plan prepared by SPCB to control and monitor secondary fugitive emissions from all the sources.
29. Determination of atmospheric inversion level at the project site and assessment of ground level concentration of pollutants from the stack emission based on site-specific meteorological features. Air quality modelling for proposed plant.
30. Permission from competent Authority for the drawal of water. Water balance chart for existing and expansion project including quantity of effluent generated recycled and reused and effluent discharge.
31. Attempt to be made for reduction for usage of water.
32. Complete scheme of effluent treatment. Characteristics of untreated and treated effluent to meet the standard.
33. Zero discharge effluent concepts to be adopted.
34. Ground water quality monitoring minimum at 6 locations shall be carried out. Geological features and Geo-hydrological status of the study area and ecological status (Terrestrial and Aquatic).
35. The details of solid and hazardous wastes generation, storage, utilization and disposal particularly related to the hazardous waste calorific value of hazardous
waste and detailed characteristic of the hazardous waste. Action plan for the
disposal of fly ash generated from boiler shall be included.
36. Precautions to be taken during storage and transportation of hazardous chemicals
shall be clearly mentioned and incorporated.
37. Material Safety Data Sheet for all the Chemicals are being used/will be used. CAS
No./RTECS No./DOT/UN etc to be mentioned against each chemicals.
38. Authorization/Membership for the disposal of solid/hazardous waste in TSDF.
39. Risk assessment for storage for chemicals/solvents. Action plan for handling &
safety system.
40. An action plan to develop green belt in 33 % area. Layout plan for green belt shall
be provided.
41. Action plan for rainwater harvesting measures at plant site shall be included to
harvest rainwater from the roof tops and storm water drains to recharge the ground
water.
42. Details of occupational health programme.
   i) To which chemicals, workers are exposed directly or indirectly.
   ii) Whether these chemicals are within Threshold Limit Values (TLV)/ Permissible
       Exposure Levels as per ACGIH recommendation.
   iii) What measures company have taken to keep these chemicals within PEL/TLV.
   iv) How the workers are evaluated concerning their exposure to chemicals during
       pre-placement and periodical medical monitoring.
   v) What are onsite and offsite emergency plan during chemical disaster.
   vi) Liver function tests (LFT) during pre-placement and periodical examination.
43. Details of occupational health surveillance programme.
44. Socio-economic development activities shall be in place.
45. Note on compliance to the recommendations mentioned in the CREP guidelines.
46. Detailed Environment management Plan (EMP) with specific reference to details of
   air pollution control system, water & wastewater management, monitoring frequency,
   responsibility and time bound implementation plan for mitigation measure shall be
   provided.
47. EMP shall include the concept of waste-minimization, recycle / reuse / recover
   techniques, Energy conservation, and natural resource conservation.
48. Total capital cost and recurring cost/annum for environmental pollution control
   measures.
49. Corporate Environmental Responsibility
   (a) Does the company have a well laid down Environment Policy approved by its
       Board of Directors? If so, it may be detailed in the EIA report.
   (b) Does the Environmental Policy prescribe for standard operating
       process/procedures to bring into focus any infringement / deviation / violation of the
       environmental or forest norms / conditions? If so, it may be detailed in the EIA
       report.
   (c ) What is the hierarchical system or Administrative order of the company to deal
       with the environmental issues and for ensuring compliance with the EC conditions.
       Details of this system may be given.
   (d) Does the company have a system of reporting of non compliance / violations of
       environmental norms to the Board of Directors of the company and / or shareholders
       or stakeholders at large? This reporting mechanism should be detailed in the EIA
       report.
50. Any litigation pending against the project and/or any direction/order passed by any
    Court of Law against the project, if so, details thereof.
51. Public hearing issues raised and commitments made by the project proponent on
    the same should be included separately in EIA/EMP Report in the form of tabular
    chart.
52. A tabular chart with index for point wise compliance of above TORs.

The following general points shall be noted:
   i.  All documents shall be properly indexed, page numbered.
   ii. Period/date of data collection shall be clearly indicated.
   iii. Authenticated English translation of all material provided in Regional languages.
   iv. The letter/application for EC shall quote the MOEF file No. and also attach a copy
       of the letter.
v. The copy of the letter received from the Ministry shall be also attached as an annexure to the final EIA-EMP Report.

vi. The final EIA-EMP report submitted to the Ministry must incorporate the issues in this letter. The index of the final EIA-EMP report must indicate the specific chapter and page no. of the EIA-EMP Report.

vii. Certificate of Accreditation issued by the QCI to the environmental consultant shall be included.

3.0 These ‘TORs’ should be considered for the preparation of EIA / EMP report for expansion of Synthetic Organic Chemicals Manufacturing Unit at Village Dothigudem, Mandal Pochampally, District Nalgonda, Andhra Pradesh in addition to all the relevant information as per the ‘General Structure of EIA’ given in Appendix III and IIIA in the EIA Notification, 2006. The EIA/EMP as per TORs should be submitted to the Chairman, Andhra Pradesh Pollution Control Board, (APPCB) for public consultation. The APPCB shall conduct the public hearing/public consultation as per the provisions of EIA notification, 2006.

4.0 You are requested to kindly submit the final EIA/EMP prepared as per TORs and incorporating all the issues raised during Public Hearing / Public Consultation to the Ministry for considering the proposal for environmental clearance within 2 years as per the MoEF O.M. No. J-11013/41/2006-IA.II (I) dated 22nd March, 2010.

5.0 The consultants involved in the preparation of EIA/EMP report after accreditation with Quality Council of India / National Accreditation Board of Education and Training (QCI/NABET) would need to include a certificate in this regard in the EIA/EMP reports prepared by them and data provided by other Organization(s)/Laboratories including their status of approvals etc.

(V.P.Upadhyay)
Director

Copy to: The Chairman, Andhra Pradesh Pollution Control Board, Paryavaran Bhavan, A-3, Industrial Estate, Sanathnagar, Hyderabad 500 018, Andhra Pradesh (E-mail: aspcb@hd2.dot.net.in; Fax No.: 040-23733261)

(V.P.Upadhyay)