

F. No. J-11011/289/2013-IA.II (I)  
Government of India  
Ministry of Environment Forest and Climate Change  
(Impact Assessment Division)

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Dated: 14<sup>th</sup> March, 2017

To

The Executive Director  
(Shri G. Manikya Reddy)  
M/s S. M. Labs Pvt. Ltd.  
Plot No. C-5, IDA, Moula Ali,  
Hyderabad, Telangana - 500 040

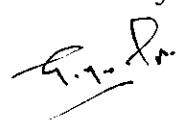
**Sub: Setting up of a Drug Manufacturing Unit (Unit-III) at Sy. No.s 1058 & 1059, Village Machanpally, Mandal Bommalramaram, District Nalgonda, Telangana by M/s S. M. Labs Pvt. Ltd. - Environmental Clearance - reg.**

**Ref: Online Proposal No. IA/TG/IND2/57846/2013 dated 27<sup>th</sup> July, 2016.**

Sir,

This has reference to your online proposal no. IA/TG/IND2/57846/2013 dated 27<sup>th</sup> July, 2016, along with project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report along with Public Hearing Report regarding the above mentioned project.

2. The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that the proposal is for setting up of a Drug Manufacturing Unit (Unit-III) at Sy. No.s 1058 & 1059, Village Machanpally, Mandal Bommalramaram, District Nalgonda, Telangana by M/s S. M. Labs Pvt. Ltd. As informed and as per the documents submitted by the Project Proponent (PP), the total plot area is 30,068 m<sup>2</sup> of which greenbelt will be developed in 17864.94 m<sup>2</sup> area. It is reported that no Eco-Sensitive Area is located within 10 km distance of the proposed manufacturing unit. Reserved forests namely Naginenipalli RF-5.2 KMs (SSW), Kondamadugu RF-6.4 KMs (SSW), Parvathipuram forest block-7.7 KMs(SW), China lakshmiapuram RF- 9.2 KMs (NNW), Mallapur RF-9.6 KMs(NNE) and Venkatapuram RF-9.7 KMs(NE) are located within 10 km distance of the unit. Water bodies namely, Shamirpetvagu-1.0 KMs (WSW), Maryalacheruvu-1.8 KMs (NW), Kottacheruvu-6.5 KMs (NNW), Jainpaliicheruvu-7.0 KMs(NNW), Jagayyacheruvu-7.3 KMs(NNW) and Bibinagarcheruvu-9.8 KMs(NNW) are located within 10 km distance from the unit. The total cost of the project will be ₹ 12.98 crore, out of which ₹ 2.0 Crore and ₹ 16.5 lakh are earmarked towards capital cost and recurring cost per annum for implementation of EMP. The following products will be manufactured by the company:



Sl.No.	Product	CAS No.	Application	Quantity (Kg/Month)
1	5-Cyano Pthalamide	82104-74-3	Drug Intermediate	10000.00
2	Atorvastatin Calcium	134523-03-8	Lipid-lowering agent	2000.00
3	Escitalopram Oxalate	219861-08-2	Antidepressant.	2000.00
4	Lamivudine	134678-17-4	Antiretroviral	2000.00
5	Lansoprazole	103577-45-3	Antiulcer	3000.00
6	Levocetirizine Di Hydrochloride	130018-87-0	Antihistamine	2000.00
7	Losartan Potassium	12470-99-8	Antihypertensive	3000.00
8	Metformin Hydrochloride	1115-70-4	Hypoglycemic	20000.00
9	Sildenafil Citrate	171599-83-0	Anti-erectile dysfunction agent	2000.00
10	Zidovudine	30516-87-1	Antiretroviral	2000.00
			Total	48000.00

3. All Synthetic organic chemicals industry projects (Bulk drugs and intermediates excluding drug formulations), located outside the notified industrial area/estate are listed at Sl.No. 5(f) of Schedule of Environmental Impact Assessment (EIA) Notification under Category 'A' and are appraised at Central Level by Expert Appraisal Committee (EAC).

4. The project proposal was considered by the Expert Appraisal Committee (Industry -2) in its 19<sup>th</sup> meeting held during 28<sup>th</sup> - 30<sup>th</sup> May, 2014 and 13<sup>th</sup> meeting held during 26<sup>th</sup> - 27<sup>th</sup> September, 2016. The Project Proponent and the accredited consultant M/s Right Source Industrial Solutions Pvt. Ltd., Hyderabad, gave a detailed presentation on the salient features of the project and proposed environmental protection measures to be undertaken, as per Terms of References (TORs) awarded in the 19<sup>th</sup> Meeting held during 28<sup>th</sup> - 30<sup>th</sup> May, 2014 for preparation of EIA-EMP report.

5. Public Hearing for the proposed project has been conducted by the Telangana State Pollution Control Board on 25<sup>th</sup> May, 2016. The issues were raised regarding emissions standard, local employment, industrial pollution and effect on crops etc. The Committee noted that issues have satisfactorily been responded by the project proponent and incorporated in the final EIA-EMP report.

6. The Project Proponent has informed the EAC that the ambient air quality monitoring was carried out at 8 locations during October, 2014 to December 2014. The baseline data indicates that the ranges of concentrations are as follows: PM<sub>10</sub> (40.38 µg/m<sup>3</sup> to 62.52 µg/m<sup>3</sup>), PM<sub>2.5</sub> (14.22 µg/m<sup>3</sup> to 22.60 µg/m<sup>3</sup>), SO<sub>2</sub> (7.90 µg/m<sup>3</sup> to 14.52 µg/m<sup>3</sup>), NO<sub>2</sub> (12.62 µg/m<sup>3</sup> to 18.65 µg/m<sup>3</sup>) and CO (0.11 mg/M<sup>3</sup> to 0.54 mg/M<sup>3</sup>). Ambient Air Quality modeling study for point source emissions indicates that the maximum incremental ground level concentrations (GLCs) after the proposed project would be 0.93 µg/m<sup>3</sup>, 3.96 µg/m<sup>3</sup> and 5.31 µg/m<sup>3</sup> with respect to PM, SO<sub>2</sub> and NO<sub>x</sub>. The resultant concentrations are within the National Ambient Air Quality Standards (NAAQS).

7. Bagfilter along with stack height of 30 m will be provided to coal fired boiler. Scrubber will be provided to control process emissions viz. HCl, Ammonia and SO<sub>2</sub>. The EAC suggested PP to use one coal based boiler, and the other should be solar based

concentrator to reduce the carbon foot print of the industrial unit. Total water requirement will be 128.56 m<sup>3</sup>/day. Out of which fresh water requirement from ground water source will be 93.87 m<sup>3</sup>/day and remaining water requirement (34.69 m<sup>3</sup>/day) will be met from treated effluent/recycled water. Wastewater generation will be 65.33 m<sup>3</sup>/day. Industrial wastewater will be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD effluent stream will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS effluent stream will be treated in ETP followed by RO. Domestic wastewater will be disposed through soak pit followed by septic tank. Inorganic waste, MEE salt and ETP sludge will be sent to TSDF. Organic waste, spent carbon and solvent distillation residue will be sent to cement industries. Used oil will be authorized recycler/re-processors. Coal ash will be sent to brick manufacturers.

8. The EAC, in its 13<sup>th</sup> meeting held during 26<sup>th</sup>-27<sup>th</sup> September, 2016, has found that the final EIA/EMP report submitted by the PP is adequate. The EAC after detailed deliberations, on the basis of the information and presentation made by the PP, has recommended the project for environmental clearance with certain conditions.

9. Based on the proposal and information submitted by the Project Proponent, and considering the recommendation of the Expert Appraisal Committee (Industry-2), the Ministry of Environment, Forest and Climate Change hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14<sup>th</sup> September 2006, subject to the compliance of the following Specific and General Conditions:

**A. Specific Conditions:**

- i. Bagfilter and the stack of adequate height shall be provided to coal fired boiler.
- ii. Scrubber shall be provided to control process emissions viz. HCl, Ammonia and SO<sub>2</sub>. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.
- iii. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits imposed by SPCB. Odour management plan shall be implemented.
- iv. Total fresh water requirement from ground water source shall not exceed 93.87m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA.
- v. Industrial effluent generation shall not exceed 65.33m<sup>3</sup>/day. Trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream shall be treated in ETP and then passed through RO system. Condensate and recover water will be recycled/reused within factory premises. 'Zero' effluent discharge shall be adopted and no effluent will be discharged outside the premises.
- vi. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- vii. As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers/cement industry.



- viii. The company shall obtain authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from SPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire-fighting facilities in case of emergency.
- ix. Fly ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
- x. Solvent management shall be as follows :
  - (a). Reactor shall be connected to chilled brine condenser system
  - (b). Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
  - (c). The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
  - (d). Solvents shall be stored in a separate space specified with all safety measures.
  - (e). Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - (f). Entire plant where solvents are used shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- xi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xii. All the issues raised during the Public Hearing/consultation meeting held on 25<sup>th</sup> May, 2016 shall be satisfactorily implemented and adequate budget provision shall be made accordingly.
- xiii. At least 5% of the total cost of the project shall be earmarked towards the Enterprise Social Commitment (ESR) based on Public Hearing issues and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office at Chennai. As suggested, major component of ESR should be on creating check dams for water supply to farmers or drinking purposes and pond to be developed for recharge to groundwater. Five year plan with projected physical and financial progress should be submitted within 1 month to concerned district collector from the date of issue of EC.
- xiv. As proposed, green belt of 17864.94 m<sup>2</sup> shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation.

#### **B. General Conditions:**

- i. The project authorities must strictly adhere to the stipulations made by the Telangana Pollution Control Board, State Government and any other statutory authority.
- ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

- iii. The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one station is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- iv. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> November, 2009 shall be followed.
- v. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.
- vii. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
- viii. The company shall also comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.
- ix. The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villages and administration.
- x. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xi. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xii. The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/pollution control measures shall not be diverted for any other purpose.
- xiii. A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad/Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/representations, if any, were received while processing the proposal.
- xiv. The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.
- xv. The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated shall be submitted to the concerned State Pollution Control


Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional Offices of MoEF&CC by e-mail.

- xvi. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at <http://moef.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional Office of the Ministry.
- xvii. The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

10. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

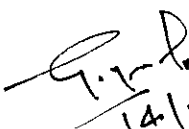
11. The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

12. The above conditions will be enforced, *inter alia* under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

  
14/3/2017  
(Yogendra Pal Singh)  
Scientist 'D'

**Copy to:-**

1. The Secretary, Department of Environment, Forests, Science and Technology, Government of Telangana, Hyderabad, Telangana
2. Additional Principal Chief Conservator of Forests (C), Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1<sup>st</sup> and 2<sup>nd</sup> Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, Chennai - 600034
3. The Chairman, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex East Arjun Nagar, Delhi - 110 032.
4. The Chairman, Telangana State Pollution Control Board, Plot No A 3, Paryavaran Bhawan, Sanath Nagar, Hyderabad - 500018, Telangana.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh, New Delhi - 110 003.
6. Guard File/Monitoring File/Website/Record File.

  
14/3/2017  
(Yogendra Pal Singh)  
Scientist 'D'