

F. No. J-11011/20/2013- IA II (I)
Government of India
Ministry of Environment, Forests and Climate Change
(I.A. Division)

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Dated: 26th March , 2015

To,

✓ Shri S. Prasad (Managing Director)
M/s Raichur Laboratories Pvt. Ltd.
Flat No. 501, Vishnu Homes, H.No. 8-3-236/1,
Near Check Post, Yosufguda, Hyderabad- 500045

E-mail: info@rightsource.co.in ; Fax No.: 040-23070602

Subject: Bulk Drug Manufacturing Unit at Plot No.126 to 129, Raichur Growth Centre, Village Chiksugaur, District Raichur, Karnataka by M/s Raichur Laboratories Pvt. Ltd. – Environmental Clearance reg.

Ref. : Your letter no. nil dated 7th July, 2014.

Sir,

This has reference to your proposal dated 7th July, 2014 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report, public hearing report on the above mentioned subject.

2.0 The Ministry of Environment, Forests and Climate Change has examined the application. It is noted that the proposal is for setting up of bulk drug manufacturing unit at Plot No.126 to 129, Raichur Growth Centre, Village Chiksugaur, District Raichur, Karnataka by M/s Raichur Laboratories Pvt. Ltd. Total plot area is 16193 m². Out of which greenbelt will be developed in 7402.85 m². Cost of project is Rs. 10.63 crore. No forest land is involved. Krishna river is flowing at distance of 8.2 Km and Konad Hall is located at a distance 1.3 Km. It is reported that no major reservoirs or ecological sensitive areas such as Bio-sphere reserves, national parks, wildlife sanctuaries, wet lands or other protected area within 10 Km distance. Following products will be manufactured:

S.N.	Product	Application	Production (Kg/Month)
1	Meropenem	Anti-Biotic	1000.00
2	Biapenem	Anti-Biotic	300.00
3	Feropenem	Anti-Biotic	1000.00
4	Imipenem	Anti-Biotic	1000.00
5	Dorepenem	Anti-Biotic	1000.00
6	Candesartan	Anti hypertension	500.00
7	Celecoxib	Anti –inflammatory	5000.00
8	Clopidogrel Bisulfate	Anti platelet	3000.00
9	Ketaconazole	Anti fungal	2000.00
10	Levo cetirizine dihydrochloride	Anti histamine	500.00
11	Levetiracetam	Anti Convulsant	3000.00
12	Pantoprazole Magnesium	Proton Pump Inhibitor	1000.00
13	Phenylephrine Hydrochloride	Anti tussive- Decongestant	3000.00
14	Prasugrel Hydrochloride	Anti platelet	500.00
15	Quetiapine Hemifumatrate	Anti psychotic	1000.00
16	Rabeprazole Sodium	Anti-ulcerative	1000.00
17	Solifenacin Succinate	Anti cholinergic	500.00
18	Tamsulosin Hydrochloride	Anti-adrenergic	1000.00

19	Telmisartan	Anti hypertensive	2000.00
20	Bortezomib	Anti neoplastic	50.00
21	Trimebutine Maleate	Anti spasmodic	500.00
22	Cabergoline	Dopamine receptor agonist	500.00
23	MycophenolateMofetil	Immuno Suppressant	500.00
24	Raloxifene Hydrochloride	Selective estrogen receptor modulator	1000.00
25	Febuxostat	Xanthine Oxidase Inhibitor	500.00

Note: we manufacture any 10 products at a point of Time and Maximum Production Capacity is 22 MT/month

3.0 Multi-cyclone followed by bag filter will be provided to the coal fired boilers to control particulate. Scrubbers will be provided to control process emissions viz. HCl, NH₃ and SO₂. Total water requirement will be 121.75 m³/day. Out of which fresh water requirement from KIADB will be 78.00 m³/day and remaining quantity 43.75 m³/day will be sourced from treated effluent. Total effluent generation will be 53.8 m³/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 reverse osmosis (RO). No effluent will be discharged outside the plant premises. Process organic residue, solvent residue and spent carbon will be sent to TSDF/cement industries. Process Inorganic residue, evaporation salts and ETP sludge will be sent to TSDF. Fly ash will be sent to brick manufacturers. Catalyst, waste oil and used batteries will be sent to the Authorised recyclers.

4.0 Public hearing was exempted as per Section 7 (i), III Stage (3), Para (i) (b) of EIA Notification, 2006.

5.0 All Synthetic Organic Chemicals Industry (Bulk Drugs & Intermediates) located inside the notified industrial area/estate are listed at S.N. 5(f) under category 'B' and appraised at State level. However, due to applicability of General Condition of interstate boundary, the proposal is treated as Category 'A' project and appraised at Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry) in its meetings held during 5th – 7th March, 2013 and 20th-21st January, 2015 respectively. Project Proponent and the EIA Consultant namely M/s Rightsource Industrial Solution Pvt. Ltd., have presented EIA / EMP report as per the TOR. EAC has found the EIA / EMP Report and additional information to be satisfactory and in full consonance with the presented TORs. The Committee recommended the proposal for environmental clearance.

7.0 Based on the information submitted by the project proponent, the Ministry of Environment and Forests hereby accords environmental clearance to above project under the provisions of EIA Notification dated 14th September 2006, subject to the compliance of the following Specific and General Conditions:

A. SPECIFIC CONDITIONS:

- i) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.

- ii) Multi-cyclone followed by bag filter shall be provided to the coal fired boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.
- iii) Two stage scrubber with caustic lye media solution shall be provided to process vents to control SO₂. Two stage scrubber with chilled water media shall be provided to process vents to control NH₃. Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. 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.
- iv) Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM_{2.5}, PM₁₀, SO₂, NO_x, VOC, CO, NH₃ and HCl shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MOEF, the respective Zonal office of CPCB and the State Pollution Control Board (SPCB).
- v) In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the SPCB.
- vi) For further control of fugitive emissions, following steps shall be followed :
 1. Closed handling system shall be provided for chemicals.
 2. Reflux condenser shall be provided over reactor.
 3. System of leak detection and repair of pump/pipeline based on preventive maintenance.
 4. The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
 5. Cathodic protection shall be provided to the underground solvent storage tanks.
- vii) The gaseous emissions from DG set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
- viii) Solvent management shall be carried out as follows :
 - i. Reactor shall be connected to chilled brine condenser system
 - ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - iv. Solvents shall be stored in a separate space specified with all safety measures.
 - v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.

- vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- vii. All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- ix) Total fresh water requirement from KIADB water supply shall not exceed 78.04 m³/day and prior permission shall be obtained from the Competent Authority.
- x) Effluent generation shall not exceed 53.8 m³/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.
- xi) 'Zero' effluent discharge shall be adopted and no effluent shall be discharged outside the premises.
- xii) Continuous Online (24x7) monitoring system of flow and pollutants to be installed in the treatment system and made available to SPCB and company's web site
- xiii) Process effluent/any wastewater shall not be allowed to mix with storm water. Storm water drain shall be passed through guard pond.
- xiv) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
- xv) 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.
- xvi) 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 TPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
- xvii) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All Transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
- xviii) Fly ash should be stored separately as per CPCB guidelines so that it should not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing alongwith the storm water. Direct exposure of workers to fly ash & dust should be avoided.
- xix) The company shall undertake following waste minimization measures :-
 - a. Metering and control of quantities of active ingredients to minimize waste.
 - b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - c. Use of automated filling to minimize spillage.
 - d. Use of Close Feed system into batch reactors.
 - e. Venting equipment through vapour recovery system.
 - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.

- xx) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.
- xxi) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xxii) As proposed, green belt over 33 % of the total project area 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 with the DFO.
- xxiii) At least 5 % of the total cost of the project shall be earmarked towards the Enterprise Social Commitment 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 Bangalore. Implementation of such program shall be ensured accordingly in a time bound manner.
- xxiv) The Company shall submit within three months their policy towards Corporate Environment Responsibility which shall inter-alia address (i) Standard operating process/ procedure to bring into focus any infringement/deviation/violation of environmental or forest norms/conditions, (ii) Hierarchical system or Administrative order of the Company to deal with environmental issues and ensuring compliance to the environmental clearance conditions and (iii) System of reporting of non compliance/violation environmental norms to the Board of Directors of the company and/or stakeholders or shareholders.
- xxv) Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.

B. GENERAL CONDITIONS:

- i. The project authorities shall strictly adhere to the stipulations made by the Karnataka State Pollution Control Board.
- ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. 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 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).

- v. 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.
- vi. 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.
- vii. Usage of Personnel Protection Equipments (PPEs) by all employees/ workers shall be ensured.
- 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. As proposed, the company shall earmark Rs. 97 Lakhs and Rs. 12.5 Lakhs are earmarked toward capital cost and recurring cost/annum to implement the conditions stipulated by the Ministry of Environment and Forests 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, Zila Parisad/Municipal Corporation, Urban local Body and the local NGO, if any, from who 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, the respective Zonal Office of CPCB and the Karnataka State Pollution Control Board. 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 31st 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 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://envfor.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.

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

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

10.0 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.

11.0 Environmental Clearance is issued to M/s Raichur Laboratories Pvt. Ltd for Bulk Drug Manufacturing Unit at Plot No.126 to 129, Raichur Growth Centre, Village Chiksugaur, District Raichur, Karnataka.


(Lalit Bokolia)
Additional Director

Copy to :-

1. The Secretary, Department of Environment & Ecology, Govt. of Karnataka, Room No. 708, Gate 2, Multi Storied Building, Dr. AmbedkarVeedhi, Bangalore - 560 001 secyenv-fee@karnataka.gov.in
2. The Chief Conservator of Forests, Regional Office (Southern Zone, Bangalore)KendriyaSadan, 4th Floor, E&F Wing, II Block Koramangala, Bangalore-560034.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.
4. The Chairman, Karnataka State Pollution Control Board, #49, ParisaraBhavana, Church Street, Bangalore-01 (Karnataka).
5. Monitoring Cell, Ministry of Environment, Forests and Climate Change , Indira Paryavaran Bhavan, Jor Bagh, New Delhi.
6. Guard File/Monitoring File/Record File.


(Lalit Bokolia)
Additional Director