

F. No. J-11011/182/2011- IA II.(I)
Government of India
Ministry of Environment, Forests and Climate Change
(I.A. Division)

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Dated: 13th March , 2015

To,
Shri M. Narayana Reddy, Managing Director
M/s Covalent Laboratories Private Limited
8-3-677/18, Shri Krishna Devaraya Nagar
Yellareddyguda, Hyderabad-500 073, Andhra Pradesh.

E-mail: covalentlabs@rediffmail.com; info@covalentlab.com; Fax No.: 040-23738496.

Subject: Bulk Drugs & Intermediate Unit (2431 TPA) and CPP (3 MW) of M/s Covalent Laboratories at Sy No. 14/4A & B, 18 to 24 at Village Maruvada, Mandal Ranasthalam, Dist. Srikakulam, Andhra Pradesh – Environmental clearance reg.

Ref. : Your letter No. CLPL—Unit-II/MoEF/EC/2014 dated 06.05.2014.

Sir,

This has reference to your letter dated 06.05.2014 (received in the MoEF on 09.05.2014) alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report, public hearing report and subsequent submission of additional information vide letters dated 29th May, 2014 regarding above mentioned project.

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 Drugs & Intermediate Unit (2431 TPA) and CPP (3 MW) of M/s Covalent Laboratories at Sy No. 14/4A & B, 18 to 24 at Village Maruvada, Mandal Ranasthalam, Dist. Srikakulam, Andhra Pradesh. Total plot area is 19.22 ha. (47.5 acres) of which, greenbelt will developed in 6.59 ha. Total cost of the project is Rs. 220 crores. Rs. 40 crores and Rs.20 crores are earmarked towards capital cost and recurring cost/annum for environmental protection measures. It is reported that no national parks/wildlife sanctuary is locate within 10 km distance. One reserve forest (RF) exists viz., Kumili Reserve Forest (8 Km). It is proposed to manufacture 24 out of 64 bulk drugs & their intermediates on campaign basis with a production capacity of 2431 TPA. The following products will be manufactured:

S. N.	Product Name	Quantity (TPA)	Therapeutic Category
I. CEPHALOSPORINS			
1	CefditorenPivoxil	50.4	
2	CeptametPivoxil	10.2	
3	Cefoperazone Sodium	15.0	
4	CefcapenePivoxil	10.2	
5	Ceftiofur Hydrochloride	5.4	
6	Citicoline Sodium	5.4	
7	Ceftizoxime Sodium	5.4	
8	Piperacillin	40.2	
9	Tazobactam	30.0	

10	Cephalothin Sodium	40.2	Antibiotic	
11	Cefoxitin Sodium	20.4		
12	Cephalonium Sulfate	45.0		
13	Ceftibuten	20.4		
14	Cefpodoxime Proxetil	120.0		
15	Cefuroxime Axetil	240.0		
16	Cefixime Trihydrate	252.0		
17	Cefdinir	60.0		
18	Cefprozil Monohydrate	40.2		
19	Cefepime Dihydrochloride Monohydrate	15.0		
20	Cefuroxime Sodium	36.0		
21	Cefazolin Sodium	15.0		
22	Aztreonam	10.2		
23	Cefotaxime Sodium	50.4	Antibiotic	
24	Ceftriaxone Sodium	40.2		
25	Cefpirome Sulfate	15.0		
26	Ceftazidime Pentahydrate	15.0		
I. PENAMS				
27	Meropenem	100.2		Antibiotic
28	Imipenem	50.4		
29	Cilastain Sodium	50.4		
30	Ertapenem Sodium	10.2		
31	Doripenem Monohydrate	10.2		
32	Biopenem	10.2		
33	Faropenem Sodium	10.2		
II. ONCOLOGY				
34	Carboplatin	40.2	Antineoplastic	
35	Cisplatin	30.0		
36	Daunprubicin Hydrochloride	20.4		
37	Idarubicin Hydrochloride	20.4		
38	Vinblastine	20.4		
39	Vincristine	20.4		
40	Navelbine	10.2		
41	Paclitaxel	10.2		
42	Docetaxel	10.2		
43	Erlotinib Hydrochloride	20.4		
III. ANTIVIRALS				
44	Adefovir Dipivoxil	150.0	Antiviral	
45	Entecavir	150.0		
46	Famciclovir	120.0		
47	Ganciclovir	150.0		
48	Oseltamivir	50.4		
49	Valecyclovir Hydrochloride	80.4		
50	Valganciclovir Hydrochloride	100.2		
51	Zanamivir	100.2		
52	Nevirapine	100.2		
53	Stavudine	400.2		
IV. Citalopram Hydrobromide				
54	Citalopram Hydrobromide	20.4	Antidepressant	
V. NON ANTIBIOTICS				
55	Aripiprazole Sulfate	100.2		
56	Duloxetine Hydrochloride	60.0		
57	Eszopiclone	50.4		
58	Modafinil	50.4		

59	Naratriptan Hydrochloride	60.0	Antipsychotic
60	Tadalafil	60.0	
61	Donepezil Hydrochloride Monohydrate	75.0	
62	Amitriptyline Hydrochloride	50.4	
63	Carprofen	50.4	
64	Fenoprofen Calcium	25.2	
	Total Productions capacity on various combination (i.e, any 24 products at a point of time)	2430.6 (~2431)	
	Captive coal based Power Plant	3 MW	

3.0 ESP along with stack of adequate height shall be provided to coal fired (30 TPH) and Multicyclone dust collector followed by bag filter shall be provided to the boiler (2 x 10 TPH) to control particulate emissions. Scrubbers will be provided to control process emissions viz. HCl, SO₂, H₂S, Cl₂ and HBr. Water requirement will be 1443m³/day. Out of which, 938 m³/day water will be met from ground water source and remaining 505m³/day water will be met from treated effluent/recycled water. Industrial effluent generation will be 884m³/day. Industrial wastewater will be segregated into High TDS/COD and Low TDS/COD effluent streams. Process high TDS/COD effluent stream (509 m³/day) will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Condensate will be treated in ETP followed by Reverse Osmosis (RO) and treated effluent will be recycled/reused as boiler make up water and cooling tower make up. 70 m³/day of High TDS (Utilities) and 305 m³/day of Low TDS/COD effluent stream will be treated in effluent treatment plant (ETP) followed by bio assay tank and guard pond. Treated effluent will be discharged into marine after meeting the standards prescribed by the SPCB. Ash from boiler will be sold to brick manufacturers. Evaporator salts, inorganic residue and ETP sludge will be sent to TSDF. Solvent will be sent to recycler. Catalyst, waste oil and used batteries will be sent to authorised recyclers/re-processors. Rain water harvesting tanks are proposed in the project site for collecting the storm for reuse thereby reduces the fresh water requirement. DG sets (3 x 1010 KVA) will be installed. PP has submitted the recommendations of AP CZMA meeting dated 15.03.2014 for marine disposal of treated effluent through dedicated pipeline to Bay of Bengal. PP has also submitted CTE order no. 329/PCB/CFE/RO-VZM/HO/2014 dated 01.03.2014 issued by APPCB, whereby they have issued NOC for establishment of marine outfall.

4.0 Public hearing was held on 18th September, 2013 by Andhra Pradesh Pollution Control Board.

5.0 All Synthetic Organic Chemicals Industry located outside the notified industrial area/estate are listed at S.N. 5(f) under category 'A' and appraised at Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry) in its meetings held during 28th - 30th July, 2011, 18th -20th November, 2013 and 30th July, 2014 -1st August, 2014 respectively. Project Proponent and the EIA Consultant namely M/s KKB Envirocare Consultants 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) CRZ clearance for the marine disposal of the treated effluents [High TDS (Utilities; 70 m³/day) and Low TDS/COD (305 m³/day)] shall be obtained
- iii) ESP shall be provided to coal fired (30 TPH) and Multicyclone dust collector followed by bag filter shall be provided to the boiler (2 x 10 TPH) to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.
- iv) Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubbers with caustic lye media solution shall be provided to process vents to control SO₂, H₂S, Cl₂ and HBr. Two stage scrubber with chilled water media shall be provided to process vents to control NH₃. Dual scrubber with caustic lye solution will be provided to control HCl emissions. Scrubber with water /dilute HCl will be provided to control NH₃ emissions. Scrubber using caustic lye solution will be provided to control HF emissions. Scrubber using lye solution will be provided to control Cl₂, H₂S, SO₂ and HBr emissions. 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.
- v) 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, NH₃, Cl₂, H₂S, HBr 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 Andhra Pradesh Control Board (APPCB).
- vi) 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 APPCB.
- vii) 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.
- viii) 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.
- ix) 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.
- x) Total fresh water requirement from ground water source shall not exceed 938m³/day and prior permission shall be obtained from the CGWA/SGWA.
 - xi) Industrial wastewater shall be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD effluent stream shall be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Condensate shall be treated in ETP followed by RO and treated effluent will be recycled/reused as boiler make up water. Low TDS/COD effluent stream will be treated in effluent treatment plant (ETP) followed by bio assay tank and guard pond. Treated effluent will be discharged to marine. HTDS (Utilities) will be treated and discharge into the Marine after conforming the norms prescribed by SPOB.
 - xii) Treated effluent shall be passed through guard pond. Continuous Online (24x7) shall be installed to monitor pH , flow and TOC .
 - 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 APPCB 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) All the commitment made regarding issues raised during the Public Hearing/consultation meeting held on 18th September, 2013 shall be satisfactorily implemented.
 - xxiv) 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.
 - xxv) 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.
 - xxvi) 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 must strictly adhere to the stipulations made by the Andhra Pradesh Pollution Control Board (APPCB), 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 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


- stations 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 sufficient funds towards 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 AP 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.


(Lalit Bokolia)
Additional Director

Copy to :-

1. The Principal Secretary, Department of Environment, Forest, Science & Technology, Government of Andhra Pradesh, Hyderabad, A.P.
2. The Chief Conservator of Forests, Regional Office (Southern Zone, Bangalore) Kendriya Sadan, 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, Andhra Pradesh Pollution Control Board, ParyavaranBhawan, A-III, Industrial Estate, Sanath Nagar, Hyderabad - A.P.
5. Monitoring Cell, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, New Delhi.
6. Guard File/Monitoring File/Record File.


(Lalit Bokolia)
Additional Director