

F. No. J-11011/236/2006- IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

Paryavaran Bhawan
CGO Complex, Lodhi Road
New Delhi – 110 003

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Telefax:011: 2436 7668
Dated 1st November, 2006

To.

✓ Shri M. P. Yadav
General Manager
M/s Matrix Labs Limited.
1-1-151/1, IVth Floor, Sairam Towers
Alexander Road, Secunderabad
Andhra Pradesh – 500 003

Fax No: 040 – 2770 0343

Email : matrix@matrixlabsindia.com / yadavmp@matrixlabsindia.com

Sub : Expansion of Bulk Drug unit (unit 8) at Gethula, Chodavaram, Pusapatirega, Vizianagaram, A.P. by M/s Matrix Laboratories Ltd. – Environmental clearance reg.

Sir,

This has reference to your letter no. MLL – 8/MOEF/EC/06-07/001 dated 26th June, 2006 along with EIA/EMP report, questionnaire seeking environmental clearance for the above project under the Environmental Impact Assessment Notification, 1994.

2.0 The Ministry of Environment and Forests has examined your application. It is noted that the proposal is for environmental clearance of expansion of bulk drug unit (unit no. 8) to enhance capacity of the 7 drugs and manufacture 8 drugs (250.10 TPM) in 2.05 ha out of existing 27.05 ha land available at Gethula, Chodavaram, Pusapatirega, Vizianagaram, A. P. as per the details given below :

S.N.	Name of the product	Qty. (TPM)
1.	Tiaprofenic acid	3.00
2.	Naproxen Sodium	50.00
3.	Trazadon HCL	3.00
4.	Allopurinol	8.00
5.	Nebumetone	1.00
6.	Citalopram Hydrobromide	2.50
7.	Efavirenz	15.00
8.	Abacavir Sulfate	3.00
9.	Nelfinavir Mesylate	5.00
10.	Indinavir Sulfate	3.00
11.	Ciproflaxacin HCL	25.00
12.	Cytosine Methyl Ester Intermediate	16.60
13.	Zidovudine	25.00
14.	Gabapantene	40.00
15.	Naproxen Intermediate (Acetyl Yara Yara)	50.00
Total		250.10

S.N. 1-7 = Existing products, capacity to be enhanced.

S.N. 8-15 = New products to be manufactured.

3.0 Ventury scrubber will be installed to control HCl & NH₃ emissions and bag filter & multi-cyclone to control air emissions. Total ground water requirement will be 970 m³/d. The wastewater generated will be partially recycled and reused in the process and also disposed off into the sea through a pipeline as per permission and guidelines issued by the GSPCB. Incinerator will be installed to incinerate high TDS x high COD effluent. Low TDS x low COD effluent will be treated in the ETP. All other process water will be subjected to reverse osmosis. Salts generated from the MEE will be sent to TSDF. The solvent from mother liquor will be recovered and reused in the plant operations. Fly ash will be sold to local brick manufacturers.

4.0 Public hearing meeting was held on 2nd May 2006. 'Consent for Establishment' has been accorded by the A.P. Pollution Control Board (APPCB) vide letter no. APPCB/SP/VZN/S1/CFE/HO/2006 - 502 dated 23rd June 2006. Total cost of the project is Rs. 100.00 Crores.

5.0. The Ministry of Environment and Forests hereby accords environmental clearance to the above project under EIA Notification dated 27th January, 1994 as amended subsequently, subject to strict compliance of the following conditions:

A SPECIFIC CONDITIONS :

- i) The gaseous emissions (SO₂, NO_x, & HCl) and particulate matter from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- ii) Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the APPCB.
- iii) For control of process emissions generated in the from HCl, the reactors shall be provided with ventury scrubbers and stacks of appropriate height as per the CPCB guidelines. The scrubbed water after neutralization shall be sent to ETP for further treatment. Company shall provide bag filter & multicyclones to control the particulate emissions from the boilers and stack height of 30 m shall be provided for the dispersion of pollutants. VOCs shall also be monitored alongwith other parameters.
- iv) Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapours are emitted from purification tanks as fugitive emissions. Action shall be taken to reduce the emissions as far as possible. Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum and Benzene shall be replaced with alternate solvents. All venting equipment shall have vapour recovery system.
- v) Industry shall switch over to aqueous based coating film in place of use of Methylene Chloride in coating operation and to non-halogenated solvents in place of halogenated solvents in a phased manner.
- vi) Hazardous and toxic waste generated during the process like distillation residue, spent carbon, spent mixture solvents, process organic residue shall be incinerated in a properly designed incinerator with energy recovery facility. The incinerator shall meet the CPCB standards and guidelines.



vii) The company shall undertake following Waste Minimization measures :-

- Metering and control of quantities of active ingredients to minimize waste.
- Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
- Use of automated filling to minimize spillage.
- Use of "Close Feed" system into batch reactors.
- Venting equipment through vapour recovery system.
- Use of high pressure hoses for equipment clearing to reduce wastewater generation.

ix Fugitive emissions in the work zone environment, product, raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by APPCB.

x Total ground water requirement and effluent generation shall not exceed 970 m³/d and 700 m³/d respectively as per the 'permission' accorded by the State Govt. and APPCB respectively. Effort shall be made to recycle and reuse maximum treated wastewater in the process and remaining shall be disposed off into the sea through a pipeline via a marine out fall after meeting the marine disposal standards as per guidelines of APPCB. The effluent shall be segregated into high TDS and low TDS streams. The high TDS x high COD effluent shall be forced evaporated and then incinerated in the incinerator. The Low TDS x low COD effluent shall be treated in ETP through equalization, neutralization, settling and aerobic treatment methods. All other process water shall be subjected to reverse osmosis. Salts generated from the Multi-Effect Evaporator (MEE) will be sent to TSDF. The domestic waste water shall be sent to the septic tank followed by the soak pit.

xi The solid waste generated in the form of process waste including organic waste, inorganic residue, hy-flow and spent carbon from the manufacturing activity, metallic constituents added as catalysts and ETP salts shall be sent to TSDF at Visakhapatnam. Fly ash shall be sold to the brick manufacturers. The solvent from mother liquor shall be recovered and reused in the plant operations. Solid waste disposal plan shall be prepared and submitted to the CPCB for the disposal of solid waste containing soluble salts to find out alternate solution, if any.

xii The company shall adopt surface as well as roof top rain water harvesting measures to harvest the run off water for recharge of ground water. Methods shall also be adopted for the conservation of water through and recycling and reusing the treated waste water.

xiii Green belt shall be provided in an area of 20 ha. to mitigate the effects of fugitive emissions all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.

xiv Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

xv The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment. The eco-development plan should be submitted to the APPCB within three months of receipt of this letter for approval.

✓ xvi Existing Primary Health Centre shall be upgraded to ten bedded hospital for the benefit of local people.

- xvii. The environmental clearance under the Coastal Regulation Zone (CRZ) Notification, 1991 and subsequent amendments shall be obtained since proposal involves discharge of treated effluent into the sea.

GENERAL CONDITIONS :

- i. The project authorities shall strictly adhere to the stipulations made by the Andhra Pradesh Pollution Control Board.
- ii. At no time, the emissions shall exceed the prescribed limits. In the event of failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.
- iii. 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.
- iv. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
- v. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the A.P. Pollution Control Board must be obtained for collections/treatment/storage/disposal of hazardous wastes.
- vi. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) 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, Rules, 1989 viz. DBA (day time) and 70 dBA (night time).
- vii. The project proponent shall also comply with all the environmental protection measures and safeguards recommended in the EIA report.
- viii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- ix. As proposed in EIA/EMP, Rs. 12.00 Crores earmarked for the environmental protection measures shall be judiciously utilized to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government alongwith the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.
- x. The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office at Bangalore / SPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies.

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- xI. 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 Ministry's Regional Office at Bhopal.
- xII. 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.

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

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

8.0 The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Wastes (Management and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.


(Dr. P.B. RASTOGI)
Additional Director

Copy to :

1. The Secretary, State Department of Environment and Forests, Govt. of Andhra Pradesh, Mantralaya, Hyderabad, A.P.
2. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110032.
3. The Chairman, Andhra Pradesh Pollution Control Board, 2nd Floor, HUDA Complex, Maitrivaram, S.R. Nagar, Hyderabad - 500 038, Andhra Pradesh.
4. The Chief Conservator of Forests (Central), Ministry of Environment & Forest, Regional Office (SZ), Kendriya Sadan, IVth Floor, E & F Wing, 17th Main Road, Koramangla, Bangalore 560 034, Karnataka.
5. JS (CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi. - 110003.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.
7. Guard file.
8. Monitoring file.
9. Record file.


(Dr. P.B. RASTOGI)
Additional Director