

No. J-11011/80/2004-IA II(I)
Government of India
Ministry of Environment & Forests
I. A. Division

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Paryavaran Bhawan,
CGO Complex, Lodi Road,
New Delhi - 110 003

Dated the June 21, 2005

To

The Director
M/s Enal Drugs Pvt Limited
Phase-I, IDA, Jeedimetla
Hydrabad.

Subject: Bulk drug unit by M/s Enal Drugs Pvt. Limited at Industrial Development area, Jeedimetla, RangaReddy district, Andhra Pradesh - environmental clearance reg.

Sir,

This has reference to your letter no. nil dated 27th March, 2003 enclosing application and subsequent communications along with questionnaire, SSI certificate and Consent under Air and Water Acts, EIA /EMP report and clarifications dated 14.5.2004 seeking environmental clearance for the above project under Environmental Impact Assessment Notification, 1994.

2.0. The Ministry of Environment and Forests has examined your application along with EIA / EMP report. It is noted that the proposal is for environmental clearance of bulk drug unit for manufacture of Omeprazole (50kg/m) and Cyproheptadiene HCl (100 kg/m). The unit is located in an area of 0.09 ha. in District Rangareddy in Andhra Pradesh. Water requirement for the project (6.26m³/d) will be met from the private suppliers. The solid waste is generated in the form of ETP sludge (1.2 TPD) and is sent to the TSDF of Hyderabad Waste Management Project at Dundigal. NOC from the Andhra Pradesh Pollution Control Board for the products being manufactured was obtained in August, 1997. Public hearing for the project is not applicable since the unit is SSI and located in the notified industrial estate. Cost of the project is Rs.30.50 lakhs

3.0. 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 (SO_x, NO_x & HCl) 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.

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- (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 SPCB.
- (iii) For control of air emissions, the reactors shall be provided with scrubbers and stacks of appropriate heights. The company shall provide chilled water coolant condensers to all solvent storage tanks to recover the emissions from the vents while loading and unloading the storage tanks. The solvents which are not recovered shall be sent to TSDF for incineration.
- (iv) Fugitive emissions in the work zone environment, product, raw material storage area shall be regularly monitored. The emissions shall conform to the limits imposed by SPCB.
- (v) The process waste water generated (1.3 m³/d) shall be treated in the ETP of the unit for primary treatment and treated waste water meeting the norms shall be sent to CETP at Jeedimetta through tankers for further treatment. Due care shall be taken to prevent leakage of effluent while loading, unloading and transportation. Waste water manifest system shall be provided along with every tanker for proper handling of effluent.
- (vi) Solid wastes generated in the form of ETP sludge (0.12 TPD) shall be stored in the HDPE drums and sent for disposal to the common secured landfill site of M/s Hyderabad Waste Management Projects.
- (vii) The company shall develop rainwater harvesting structures to harvest the run off water for recharge of ground water.
- (viii) Green belt shall be provided in 25% of the plant area to mitigate the effects of fugitive emission all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.
- (ix) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (x) The Company shall undertake eco-development 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.

B. GENERAL CONDITIONS

- (i) The project authorities shall strictly adhere to the stipulations made by the Andhra Pradesh State 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, 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 State 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 EPA 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) The project authorities shall earmark separate funds 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 provided shall not be diverted for any other purpose.
- (x) The implementation of the project via-a-via 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.

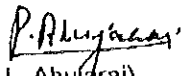
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- (xi) The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry 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 Bangalore.
- (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.

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


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

6.0. 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. L. Ahujarai)
Director

Copy to :-

1. The Secretary, State Deptt. of Environment, Government of Andhra Pradesh, Mantralaya, Hyderabad.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
3. The Chairman, Andhra Pradesh State Pollution Control Board, 2nd Floor, HUDA Complex, Maitrivaram, S.R.Nagar, Hyderabad- 500 038.
4. The Chief Conservator of Forests (Central), Regional Office (SZ), Kendriya Sadan, IVth Floor, E&F Wing, 17th Main Road, Koramangala, Bangalore-560034.
5. JS(CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.- 110003.
6. The Director (Monitoring Cell), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi- 110003.
7. Guard file.
8. Record file.
9. Monitoring file.


(Dr. P. L. Ahujarai)
Director