

Dr. R.ANNAMALAI,I.F.S.,
DIRECTOR OF ENVIRONMENT AND
MEMBER SECRETARY



STATE LEVEL ENVIRONMENT
IMPACT ASSESSMENT AUTHORITY,
TAMILNADU,
Tamilnadu Pollution Control Board Premises,
76, Mount Salai, Guindy,
Chennai- 600 032.

No.SEIAA/TN/EC/5(f)/004/F-133/2008 Dated: 5.01.2009

To

The Authorised Signatory,
M/s Actavis Pharma Manufacturing
Private Limited,
Plot No: 16, 17, 31 & 32, SIDCO
Pharmaceutical Industrial Estate,
Alathur, Chengalpattu Taluk,
Kancheepuram District

Sir,

Sub: SEIAA - Proposed change in product mix – M/s Actavis Pharma Manufacturing Private Limited, Plot No: 16, 17, 31 & 32, SIDCO Pharmaceutical Industrial Estate, Alathur, Chengalpattu Taluk, Kancheepuram District. - Environmental Clearance - reg.

This has reference to your application No. AMPL/API/ENV/08/003 dated 4.08.08 to the SEIAA, Tamil Nadu along with Form-1 and other details for the Proposed change in product mix at Plot No: 16, 17, 31 & 32, SIDCO Pharmaceutical Industrial Estate, Alathur, Chengalpattu Taluk, Kancheepuram District seeking environmental clearance under the Environment Impact Assessment Notification, 2006. The proposal has been appraised by the State Level Expert Appraisal Committee as per the prescribed procedure in the light of provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application Viz., the Application Form- I, and REIA report and the additional clarifications furnished in response to the observations of the State Level Environment Impact Assessment Authority in its meeting held on 16th & 17th September 2008 and 14th-15th, November 2008.

It is noted interalia that the project proposal is for Environmental Clearance for the manufacture of 1) Alfuzosin - 0.0167 TPM, 2) Aripiprazole – 0.0167 TPM, 3) Atrovastatine – 0.7500 TPM, 4) Bosentan – 0.0167 TPM, 5) Colpidogrel – 0.8333 TPM, 6) Duloxetine – 0.0667 TPM, 7) DMAIA – 0.0167 TPM, 8) Entacapone – 0.2083 TPM, 9) Eletriptan – 0.0417 TPM, 10) Imatinib – 0.0833 TPM, 11) Imiquimod – 0.0042 TPM, 12) Isradipine – 0.0250 TPM, 13) Irbesartan- 2.0833 TPM, 14) Lercanidipine – 0.0417 TPM, 15) Letrazole – 0.0017, 16) Levetiracetam – 0.9167 TPM, 17) Levofloxacin – 1.2500 TPM, 18) Midodrine – 0.0083 TPM,

19) Moxonidine-0.0021 TPM, 20) Nebivolol – 0.0167 TPM, 21) Nisoldipine – 0.0167 TPM, 22) Olanzapine – 0.0417 TPM, 23) Pantoprazole – 0.5000 TPM, 24) Pregabalin – 0.0167 TPM, 25) Pramipexole – 0.0017 TPM, 26) Pioglitazone – 0.1667 TPM, 27) Quetiapine – 0.4167 TPM, 28) Residronate – 0.025 TPM, 29) Rosiglitazone – 0.0333 TPM, 30) Repaglinide – 0.0083 TPM, 31) Rivastigmine – 0.0083 TPM, 32) Sildenafil – 0.0833 TPM, 33) Telmisartan – 0.2500 TPM, 34) Tizanidine – 0.0250 TPM, 35) Tolterodine – 0.0083 TPM, 36) Ziprasidone – 0.0500 TPM at Plot No: 16, 17, 31 & 32, SIDCO Pharmaceutical Industrial Estate, Alathur, Chengalpattu Taluk, Kancheepuram District by M/s Actavis Pharma Manufacturing Private Limited. The total land area of the project is 1.781 Hectares. The total cost of the project is Rs. 28.3 Lakhs. Water requirement of 63 KLD will be sourced from Private supply. The wastewater generated from process (57 KLD) will be treated in the effluent treatment plant. Domestic effluent (5 KLD) will be treated in the sewage treatment plant. The total power requirement of the project will be sourced from Tamil Nadu Electricity Board. The existing 320 KVA DG set will be replaced with 1000 KVA. The hazardous waste generated (23.77 T/Y) will be Collected and stored in a weather proof shed.

The project activity is listed at 5 (f) in the Schedule of EIA Notification, 2006 and is of B2 Category. Public Hearing/consultation not required for the project as it is located in a notified SIDCO industrial complex at SIDCO Pharmaceutical Industrial Estate, Alathur, Chengalpattu Taluk, Kancheepuram District.

The SEAC after due consideration of the relevant documents, information furnished by you, has recommended to the SEIAA, Tamil Nadu to grant Environmental Clearance to this project subject to certain conditions. The proposal was considered by SEIAA, Tamil Nadu in its meeting held on 26.12.2008 and as the public consultation is not required for the project, the SEIAA hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 based on the recommendations of the SEAC subject to the strict compliance of the following terms and conditions:

A. SPECIFIC CONDITIONS - Environment Management Measures

- i. "Consent for Establishment" shall be obtained from the Tamil Nadu Pollution Control Board and a copy shall be furnished to the SEIAA, Tamil Nadu before taking up of any construction activity at the site.
- ii. Domestic effluent and trade effluent generated from the unit shall be treated in the Sewage treatment plant and Effluent treatment plant and the treated

sewage and trade effluent shall satisfy the standards prescribed by the Tamil Nadu Pollution Control Board.

- iii. Treated sewage shall be utilized for gardening/green belt development within the premises.
- iv. Treated trade effluent shall be utilized for cooling tower makeup as committed.
- v. The Proponent shall obtain necessary permission from the competent Authority for the extraction of ground water / transport of water to the project.
- vi. The project authorities shall strictly comply with the provisions of the Manufacture, Storage and Import of Hazardous Chemicals Rules 1989, as amended in 2000 and the Public Liability Insurance Act for handling of hazardous chemicals etc. Necessary approvals from the Chief Controller of Explosives must be obtained before commissioning of the project. Requisite On-site and Off-site Disaster Management Plans shall be prepared and implemented.
- vii. The project authorities shall provide adequate funds both recurring and non-recurring to implement the Environmental Management Measures stipulated by the SEIAA along with the implementation schedule for all the conditions stipulated herein. The funds so provided should not be diverted for any other purposes.
- viii. A separate Cell with adequate, technically competent staff should be appointed to operate the Environmental Control measures and the cell should report directly to the top Executive of the plant premises.
- ix. Regular Ambient Air Quality Monitoring shall be carried out for VOC and HC besides other parameters in ambient air around the Plant. The location and results of existing monitoring stations will be reviewed in consultation with the concerned State Pollution Control Board based on the occurrence of maximum ground level concentration and downwind direction of wind. Additional Stations shall be set up, if required. It shall be ensured that at least one monitoring station is set up in up-wind & in down-wind direction along with those in other directions.
- x. Occupational health surveillance of worker shall be done on a regular basis and records maintained as per the Factories Act, 1948.
- xi. Proper House keeping and adequate occupational health programme shall be taken up. Regular Occupational Health Surveillance Programme for the relevant diseases shall be carried out and the records shall be maintained

- properly for at least 10 years. Sufficient preventive measures shall be adopted to avoid direct exposure to emission and other Hydrocarbons etc.
- xii. The proponent shall undertake periodical health monitoring of the workers with special reference to the impact on the respiratory and renal system and maintain the document and appropriate monitoring gadget to be deployed to monitor VOC.
 - xiii. The overall noise levels in and around the plant area shall be kept well within the standards prescribed by the Tamil Nadu Pollution Control Board by providing noise control measures on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under the Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
 - xiv. HCl, HBr, and Ammonia emissions from the reactors/process vents shall be provided with suitable scrubbers and condensers. Scrubber shall have minimum of 99% efficiency.
 - xv. Regular monitoring of VOC and HC in the Work Zone Area in the Plant shall be carried out and data be submitted to SEIAA and TNPCB. Quarterly monitoring of fugitive emissions shall be carried out as per the Guidelines of CPCB.
 - xvi. The Company shall harvest surface as well as rainwater from the rooftops of the buildings in the project and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water.
 - xvii. The Proponent shall furnish an undertaking that they will abide by the conditions/recommendations mentioned in the REIA report furnished by them.
 - xviii. Greenbelt shall be developed to mitigate the effect of fugitive emission all around the plant in a minimum 30% plant area in consultation with the District Forest Officer as per CPCB guidelines.
 - xix. ETP sludge Hazardous Solid waste from process shall be collected and stored in a weather proof shed. Handling and disposal of Hazardous waste should comply with TNPCB norms.
 - xx. Stringent odour control measures shall be implemented to prevent odour nuisance totally to the neighbourhood population and industrial units in a complete and adequate manner.

- xxi. It is mandatory for the project proponent to furnish to the SEIAA, Half yearly compliance report in hard and soft copies on 1st June and 1st December of each calendar year in respect of the conditions stipulated in the prior Environmental clearance.

B. GENERAL CONDITIONS:

- i) The Environmental Clearance does not absolve the applicant/proponent of his obligation/requirement to obtain other statutory and administrative clearance from the concerned statutory and administrative authorities.
- ii) No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA. In case of deviations or alterations in the project proposal from those submitted for clearance, a fresh reference shall be made to the SEIAA to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- iii) Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act,1948.
- iv) Proper House keeping programmes shall be implemented.
- v) Usage of Personal Protective Equipments (PPEs) by all employees/workers shall be ensured.
- vi) The project proponent shall also comply with all the environmental protection measures and safeguards proposed in the EMP report.
- vii) The project proponent shall advertise in at least two local newspapers widely circulated in the region, one of which shall be in the vernacular language informing the public that
 - i) The project has been accorded Environmental Clearance.
 - ii) Copies of Clearance letters are available with the Tamil Nadu Pollution Control Board.
 - iii) Environmental Clearance may also be seen on the website of the SEIAA.

The advertisement should be issued within 7 days from the date of issue of the clearance letter and a copy of the same shall be forwarded to the SEIAA.

- viii) The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

- ix) The SEIAA reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner shall implement these conditions.
- x) The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

**Member Secretary,
State Environment Impact
Assessment Authority,
Tamil Nadu.**

Copy to:-

1. The Secretary to Government, Environment & Forests Dept,
Govt.of Tamil Nadu, Fort St.George, Chennai-600 009.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan,
CBD Cum-Office Complex, East Arjun Nagar, New Delhi 110 032.
3. The Member Secretary, Tamil Nadu Pollution Control Board,
76, Mount Salai, Guindy, Chennai-600 032.
4. The CCF, Regional Office, Ministry of Environment & Forest (SZ),
Kendriya Sadan, IV floor, E&F wings, 17th Main Road,
Koramangala II Block, Bangalore – 560 034.
5. Monitoring Cell, I A Division, Ministry of Environment & Forests,
Paryavaran Bhavan, CGO Complex, New Delhi 110 003.
6. Stock File.