

F. No. J-11011/396/2011- IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

Paryavaran Bhawan
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Dated 10th September, 2012

To,

Shri M.P. Yadav, Sr. V.P. (EHS)
M/s Hetero Labs Limited.
Sanathnagar, Hyderabad-500 018
Andhra Pradesh.

E-mail : contact@heterodrugs.com ; yadavmp@heterodrugs.com ;
Fax No. : 91-40-23704926

Subject: Expansion of the Bulk Drugs by enhancement of Product Mix (60 TPM to 500 TPM) at Narasaraopuram, Nakkapally, Visakhapatnam, Andhra Pradesh by M/s Hetero Labs Limited – Unit-III (Formerly Unit-V) – Environmental Clearance reg.

Ref. : Your letter no. nil dated 29th August, 2011.

Sir,

Kindly refer your letter dated 29th August, 2011 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EMP Report alongwith public hearing report and subsequent communications vide your letters dated 30th November, 2011 and 6th June, 2012 on the above mentioned subject.

2.0 The Ministry of Environment and Forests has examined the application. It is noted that the proposal is for expansion of the Bulk Drugs by enhancement of Product Mix (60 TPM to 500 TPM) at Sy. No. 119, 120, 125 (Part), 126, 138 (Part), Village Narasaraopuram, Mandal Nakkapally, District Visakhapatnam, Andhra Pradesh. Total plot area is 60 acres. Expansion of the unit will be carried out in the existing premises. No national park/wildlife sanctuary is located within 10 Km. Reserve Forests (2 Nos) are located within 10 Km. Unit is 2.1 Km away from Bay of Bengal. Total cost of the project is Rs. 12.5 Crores. Following products will be manufactured:

S. N.	Product Name	No. of Stages	Production	
			TPM	TPD
REGULAR PRODUCTS LIST				
1	Abacavir Sulphate	2	20	0.658
2	Efavirenz	3	60	1.973
3	Escitalopram Oxalate	2	20	0.658
4	Fosamprevavir	1	30	0.986
5	Hydralazine HCL	2	50	1.644
6	Indinavir	2	50	1.644
7	Irbesartan	2	20	0.658

8	Lamivudine	3	50	1.644
9	Leviteracetam	2	25	0.822
10	Losartan Potassium	3	40	1.315
11	Maraviroc	1	20	0.658
12	Nevirapine	2	40	1.315
13	Pioglitazone HCL	3	20	0.658
14	Quetiapine Fumerate	2	40	1.315
15	Raltegravir	1	30	0.986
16	Stavudine	2	60	1.973
17	Telmisartan	2	40	1.315
18	Tenofovir Disproxil Fumerate	2	20	0.658
19	Terbinafine HCL	2	20	0.658
20	Zidovudine	2	60	1.973
Production Scenario (A)			490	16.33

10 products will be manufactured at any point of time out of 20 regular products

CAMPAIGN PRODUCTS

1	Alendronate Sodium	1	0.1	0.003
2	Aliskiren Hemifumarate	1	0.2	0.007
3	Aripiprazole	1	0.1	0.003
4	Atazanavir Sulphate	1	1	0.033
5	Atomoxetine HCL	1	0.1	0.003
6	Benezapril HCl	1	0.1	0.003
7	Butenafine HCl	1	0.02	0.001
8	Candesartan cilexetil	2	0.5	0.016
9	Cilazapril Monohydrate	2	0.1	0.003
10	Cilostazol	1	0.75	0.025
11	Darunavir	1	0.75	0.025
12	Deflazacort	1	0.05	0.002
13	Desloratadine	1	0.05	0.002
14	Didanosine	1	1	0.033
15	Emtricitabine	1	1	0.033
16	Eplerenone	1	0.05	0.002
17	Ezetimibe	1	1	0.033
18	Feropenem Sodium	1	0.1	0.003
19	Fluticasone	1	0.01	0.000
20	Lopinavir	1	1	0.033
21	Loratidine	1	0.2	0.007
22	Maliniciparm HCl	1	0.05	0.002
23	Mifepristone	1	0.1	0.003
24	Miglitol	1	0.05	0.002
25	Moxatidine	1	1	0.033
26	Nadifloxacin	1	0.02	0.001
27	Nelfinavir	1	1	0.033
28	Osaltamivir Phosphate	1	0.75	0.025
29	Ozagrel HCl	1	0.1	0.003
30	Pamidronate Sodium	1	0.1	0.003
31	Posaconazole	1	1	0.033
32	Ramipril	1	1	0.033
33	Rasagiline Mesylate	1	0.1	0.003
34	Residronate Sodium	1	0.1	0.003
35	Rufinamide	1	0.1	0.003

36	Rupatadine Fumarate	1	0.1	0.003
37	Sequinavir Mesylate	1	0.8	0.026
38	Simvastatin	1	0.8	0.026
39	Sumatriptan Succinate	1	0.1	0.003
40	Tazarotane	1	0.05	0.002
41	Tegaserod Maleate	1	0.05	0.002
42	Tiagabine	1	1	0.033
43	Ticonazole	1	0.8	0.026
44	Torsemide	1	0.25	0.008
45	Valsartan	2	1	0.033
46	Voriconazole	1	1	0.033
47	Zonisamide	1	0.2	0.007
Production Scenario (B)			10	0.33
10 products will be manufactured at any point of time out of 47 campaign products.				
Production Scenario (A+B)			500	16.66

3.0 Multi-cyclone separator followed by bagfilter alongwith stacks of adequate height will be provided to coal fired boiler. Adequate scrubbing system will be provided to the process vents to control process emissions. Total fresh water requirement from desalination plant will be increased from 247.99 m³/day to 958 m³/day after expansion. Industrial effluent generation will be increased from 182.48 m³/day to 676 m³/day after expansion. Industrial effluent 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/COD effluent stream will be treated in effluent treatment plant (ETP) comprising primary, secondary and tertiary treatment. The unit will have common effluent treatment facilities to treat the effluent generated from two units by name Hetero Labs Ltd. Unit III and Hetro Drugs Ltd. Unit VI in the neighbouring SEZ owned by a group company. The treated effluent will be disposed off to marine outfall after confirming discharge standards through guard ponds. ETP sludge, process inorganic salts and evaporation salts will be sent to Treatment Storage Disposal Facilities (TSDF) for hazardous waste. Fly ash will be sold to brick manufacturers/ cement plant. Waste oil and used batteries will be sold to authorized recyclers/re-processors.

4.0 Public hearing of the project was held on 19th May, 2011.

5.0 All synthetic organic chemical industries (bulk drugs & intermediates) located outside the notified industrial estate/area 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-2) in its 15th, 30th and 36th meetings held during 22nd-23rd October, 2010, 15th-16th December, 2011 and 11th - 12th June, 2012 respectively. 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) All the specific conditions and general conditions specified in the environmental clearance letter accorded vide Ministry's letter no. J-11011/352/2003-IA.II (I) dated 25th September, 2006 shall be implemented.

- ii) 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.
- iii) Permission and recommendation shall be obtained from the State Forest Department regarding the impact of the proposed expansion on the surrounding reserve forests (2 Nos.).
- iv) Multi-cyclone followed by bag filter shall be provided to the boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.
- v) Adequate scrubbing system shall be provided to the process vents to control process 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 should go beyond the prescribed standards. Scrubbers vent shall be provided with on-line detection and alarm system to indicate higher than permissible value of controlled parameters.
- vi) 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 PM₁₀, SO₂, NO_x, CO and VOC 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 AP Pollution Control Board (APPCB).
- vii) To eliminate/reduce odour problem, the effluent before going to ETP shall be treated in stripper for removal of VOC. VOC shall be monitored in ETP area.
- viii) Specific VOC to be monitored for the specific solvents using proper sampling and analysis protocols.
- ix) 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.
- x) 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.
- xi) 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.
- xii) 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.
- xiii) Total fresh water requirement from desalination plant will be 958 m³/day after expansion and prior permission shall be obtained from the concerned Authority. No ground water shall be used.
- xiv) 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 agitated thin film drier (ATFD). Low TDS effluent stream shall be treated in ETP and then passed through RO system. The unit will have common effluent treatment facilities to treat the effluent generated from two units by name Hetero Labs Ltd. Unit III and Hetro Drugs Ltd. Unit VI in the neighbouring SEZ owned by a group company. The treated effluent shall be disposed off to marine outfall after conforming to the standards prescribed for the effluent discharge and obtaining permission from the APPCB. Water quality of treated effluent shall be monitored regularly and monitoring report shall be submitted to the APPCB. No process effluent shall be discharged in and around the project site. Sewage shall be treated in sewage treatment plant.
- xv) The effluent containing solvent going to bioreactor (ETP) shall be removed by steam stripping. Unit shall ensure that no solvent enters the biological ETP, their it is toxic to the biomass.
- xvi) The treated effluent having TDS above 7000 – 8000 mg/lit shall be passed through separate RO. Permeate of RO shall be reused/recycled in the process.
- xvii) Treated industrial effluent shall be passed through guard pond. The guard pond shall have online pH, TOC analyser and flowmeter and data shall be online transmitted to the APPCB website.
- xviii) 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.
- xix) 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.
- xx) Waste organic residue having very high calorific value which is being sent to cement plant for co-processing requires complete audit. The study shall include how waste are fed into the kiln and other associated problems. The study report shall be submitted to Ministry's Regional Office at Bangalore, APPCB and CPCB within three months.
- xxi) The salt from drier contains 3-4 % organic matter. A study shall be carried out to treat it in a rotary kiln (above 800 °C) to remove organics and utilization of salt shall be explored. The study report shall be submitted to Ministry's Regional Office at Bangalore, APPCB and CPCB within six months.
- xxii) 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.

- xxiii) 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.
- xxiv) Fly ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
- xxv) 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.
- xxvi) 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.
- xxvii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xxviii) The recommendation of the study conducted by NIO should be implemented in a time bound manner.
- xxix) All the issues raised during the public hearing/consultation meeting held on 19th May, 2011 shall be satisfactorily implemented.
- xxx) As proposed, greenbelt shall be developed in 20 acres out of total land 60 acres. Selection of plant species shall be as per the CPCB guidelines.
- xxxi) As for CSR activity, two ponds near temple shall be upgraded.
- xxxii) 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, mobile sewage treatment plant, 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 A. P. 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 adequate funds towards capital cost and recurring cost 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 A. P. 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 Wastes (Management and Handling) Rules, 1989/2003/ 2008 and the Public Liability Insurance Act, 1991 alongwith their amendments and rules.


(Dr. P L Ahujarai)
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, Paryavaran Bhawan, A-III, Industrial Estate, Sanath Nagar, Hyderabad - A.P.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Guard File/Monitoring File/Record File.


(Dr. P L Ahujarai)
Director