State Level Environment Impact Assessment Authority (SEIAA)
Telangana State
Government of India
Ministry of Environment, Forests & Climate Change
A-3, Industrial Estate, Sanathnagar, Hyderabad - 500 018.

REGD.POST WITH ACK.DUE

Order No. SEIAA/TS/MDK-31/2015- 1715 **Dt:10.11.2015.**

Sub: SEIAA, TS – M/s. Hetero Labs Ltd., Unit-I, Sy. No. 10 (P), Gaddapotharam, IDA, Jinnaram (M), Medak District – Environmental Clearance - Issued - Reg.

I. This has reference to your application submitted vide letter dt. 12.11.2012 & subsequent lrs. dt. 08.08.2013, 29.10.2013 & 29.10.2015 seeking Environmental Clearance for the proposed expansion of **Synthetic Organic Chemicals manufacturing unit** in the name of **M/s. Hetero Labs Ltd., Unit-I, Sy. No. 10 (P), Gaddapotharam, IDA, Jinnaram (M), Medak District.** The nearest human habitation viz., Gaddapotharam (V) exists at a distance of 2.2 km from the project site. The Sub-Committee constituted by the SEAC reported that the industry is located at a distance of 5.19 km from the nearest Critically Polluted Area i.e., IDA Patancheru - Bollaram. The total area of the site is Ac. 35.0, out of that area earmarked for Green belt is Ac. 16.5. The total cost of the project is 35.0 Crores and the production capacities of the project after expansion is as following:

S.No	Name of the product	Production Capacity	
		Kg/Month	Kg/Day
1	**Abcavir Sulphate**	**4000**	**133.3**
2	Anastrazole	90	3
3	Aripiprazole	650	21.7
4	Atazanavir Sulphate	700	23.3
5	Atomoxetine Hydrochloride	200	6.7
6	**Atorvastatin Calcium**	**4000**	**133.3**
7	Bendamustine Hydrochloride	1	0.033
8	**Bicalutamide**	**2000**	**66.7**
9	Bortezomib	1	0.033
10	Candesartan	750	25
11	**Capecitabine**	**2000**	**66.7**
12	Cilzapril Monohydrate	120	4
13	Cyclophosphamide	350	11.7
14	Darunavir	570	19
15	Dasatinib	100	3.3
16	**Desloratadine**	**1300**	**43.3**
17	Didanosine	60	2
18	Doxorubucin	20	0.7
19	Dutasteride	200	6.7
20	**Effavirenz**	**9000**	**300**
21	**Emtricitabine**	**4000**	**133.3**
22	Eplerenone	200	6.7
23	Erlotinib HCl	500	16.7
24	**Escitalopram**	**5000**	**166.7**
25	Etravirine	500	16.7
26	Exemestane	200	6.7
27	Ezetimide	1200	40
28	Finasteride	270	9
29	Fludarabine	3	0.1
30	Fulvestrant	15	0.5
31	Gefitinib	500	16.7
32	Gemcitabine HCl	220	7.3
33	**Hydralizine HCl**	**3400**	**113.3**

S.No	Name of the product	Production Capacity	
		Kg/Month	Kg/Day
34	Imatinib	1100	36.7
35	**Irbesartan**	**8800**	**293.3**
36	Irinotecan HCl	20	0.7
37	**Lamivudine**	**12000**	**400**
38	Lapatanib	100	3.3
39	Lenalidomide	100	3.3
40	Letrozole	54	1.8
41	**Levitracetam**	**24000**	**800**
42	**Lopinavir**	**2500**	**83.3**
43	**Losartan Potassium**	**11000**	**366.7**
44	Marovirac	460	15.3
45	Milnacipran	500	16.7
46	**Nelfanivir Mesylate**	**1275**	**42.5**
47	**Nevirapine**	**23000**	**766.7**
48	Nilotinib	20	0.7
49	Olmisartan	1125	37.5
50	Pazopanib	200	6.7
51	Pioglitazone HCl	5	0.2
52	Premetrexed Disodium	720	24
53	**Quetiapine**	**9600**	**320**
54	Ramipril	1200	40
55	**Saquanavir Mesylate**	**1500**	**50**
56	**Simvastatin**	**5000**	**166.7**
57	Sorefinib	200	6.7
58	**Stavudine**	**4000**	**133.3**
59	Sunitinib	200	6.7
60	**Telmisartan**	**6000**	**200**
61	**Temzolomide**	**7700**	**256.7**
62	**Tenofovir**	**4000**	**133.3**
63	**Terbinifine**	**5000**	**166.7**
64	Thalidomide	300	10
65	**Torsemide**	**1400**	**46.7**
66	**Valsartan**	**7560**	**252**
67	Vinorelabine	10	0.3
68	Voricanozole	1200	40
69	Vorinostat	5	0.2
70	**Zidovudine**	**9000**	**300**
71	Zoledronic Acid	460	15.3
72	Zonisamide	750	25
Total (Worst Combination of any 27)*		**178035**	**5934.5**
Captive Coal based Power Plant		**2 MW**	

**** Only 27 products can be manufactured at any point of time.***

II. In the process, synthetic organic chemicals are produced by using various chemicals, solvents.

III. The proposal has been examined and processed in accordance with EIA Notification, 2006 and its amendments thereof. The State Level Expert Appraisal Committees (SEAC) examined the proposal in its meetings held on 03.12.2012, 16.01.2013, 29.06.2013, 30.07.2013, 28.08.2013, 06.07.2015 & 15.09.2015. The project is exempted from the process of Public Hearing as the industry is located in a Notified Industrial Area existing since 1990's, as per G.O.Ms. No. 80, I&C(IP&INF) Dept., dt. 27.10.2015. The Sub-Committees constituted by the SEACs inspected the site on 21.04.2013 & 07.07.2015 and submitted the reports. The SEAC observed that it is a project involving violation as the project proponent was involved in manufacturing un-consented products and excess production without obtaining prior EC. Hence, the proposal was examined

keeping in view of OMs dt. 16.11.2010, 12.12.2012 & 27.06.2013 issued by the MoE&F, GoI. Based on the information furnished, presentation made by the proponent and the consultant M/s. Team Labs & Consultants, Hyderabad; Certified Compliance Report dt. 05.11.2012 issued by the Regional Office, MoE&F, GoI, as per Circular dt.30.05.2012 of MoE&F, GoI; reports of the Sub-Committees; G.O.Ms. No. 95, dt. 21.09.2007 of the EFS&T Dept., GoAP; G.O.Ms. No. 64, dt. 25.07.2013 of the EFS&T Dept., GoAP; G.O.Ms. No. 120, dt. 22.10.2013 of the I&C Dept., GoAP; G.O.Ms. No. 80, dt. 27.10.2015 of the I&C Dept., GoTS; OM dt. 10.12.2014 of the MoEF&CC, GoI w.r.t. exemption of Public Hearing; OMs dt.13.01.2010, 17.09.2013 & 10.06.2014 of MoE&F, GoI w.r.t. moratorium on Patancheru – Bollaram; S.O.1599 (E) dt.25.06.2014 amending EIA Notification, 2006 w.r.t. modification in general condition reducing distance of the project from Critically Polluted Area; legal opinion furnished by the Standing Counsel of APPCB, National Green Tribunal, Chennai on 24.09.2013; Orders dt.22.12.2014 & 09.03.2015 in M.A.No.302/2014 filed in the Hon'ble National Green Tribunal (NGT); Lr. dt. 02.06.2015 of the Principal Secretary to the Govt., EFS&T Dept., informing that credible action has been initiated against the proponent for violation, the Committee considered the project proposal and recommended for issue of Environmental Clearance. The State Level Environment Impact Assessment Authority (SEIAA) in its meetings held on 22.12.2012, 24.10.2013, 04.07.2015, 15.10.2015 & 07.11.2015 examined the proposal and recommendations of SEAC for issue of Environmental Clearance for Expansion. Accordingly, after discussions in the matter and considering the recommendations of the SEAC, **the SEIAA, Telangana hereby accords Environmental Clearance to the project for Expansion** as mentioned at Para no. I under the provisions of the EIA Notification 2006 and its subsequent amendments issued under Environment (Protection) Act, 1986 subject to implementation of the following specific and general conditions:

A. Specific Conditions:

i. Air pollution:

i The emissions from the coal fired Boilers of capacities 8 TPH (existing - as standby) & 20 TPH (proposed), shall be routed through bag filters followed by stacks of height 30 m & 40 m respectively. The concentration of particulates in the emission from the proposed boiler shall not exceed 50 mg/Nm^3. Sampling Port with removable dummy of not less than 15cm diameter in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc, shall be provided to monitor stack emissions. Stacks with adequate height shall be provided for D.G. Sets of capacities 2 x 320 kVA (existing), 1 x 500 kVA (existing) & 3 x 1020 kVA (proposed) as per CPCB norms.

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 The process emissions containing Hydrogen Chloride, Ammonia and Sulphur Dioxide shall be routed through two stages scrubber system. Scrubbed liquid shall be treated and reused or subjected to MEE. The process emissions containing derivatives of Hydrogen, Butane, Carbon dioxide & Oxygen shall be dispersed into the atmosphere

iv Necessary measures shall be taken to control odour as far as possible. Chillers (brine solution) shall be installed to reduce solvent evaporation losses into the atmosphere. All the solvent storage tanks shall be connected to vent condensers. Regular monitoring of the VOCs shall be carried out using sensors.

v The solvents shall be recovered by installing fractional distillation columns. The recovered solvents shall be reused in the process or sold to recyclers authorized by TSPCB. The volatile vapours generated during process shall be routed through condensers and the condensate shall be reused in the plant.

vi As proposed, green belt of Ac.16.5 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.

vii Raw materials shall be transported in covered trucks. Raw materials shall be stored under sheds. All the belt conveyors shall be covered with G.I. sheets. Appropriate dust suppression system shall be provided all around the stockpiles and conveyor system. All the roads in the plant area shall be asphalted / concreted and water shall be sprinkled to suppress the dust.

viii Ambient air quality including ambient noise levels must not exceed the standards stipulated under Notification dt. 16.11.2009 issued by the MoE&F, GoI. Monitoring of ambient air quality and stack emissions shall be carried out regularly in consultation with TSPCB.

b) Water Pollution:

i The source of water is Bore-wells within plant site. The total water requirement after expansion shall not exceed 834 KLD. Quantity of water used for: Process is 159.0 KLD; washings is 10.0 KLD; boiler make-up is 90.0 KLD; Cooling tower makeup is 415.0 KLD; Pre-treatment of water in RO/DM Plant 60.0 KLD; Scrubber is 10.0 KLD; Domestic purposes is 50.0 KLD & Gardening is 40.0 KLD.

ii The total waste water generated after expansion is 310.3 KLD. Out of that, 175.3 KLD is from Process; 10.0 KLD is from washings; 5.0 KLD is from Boiler blow down; 10.0 KLD is from cooling tower bleed of; 60.0 KLD is from Pre-treatment of water in RO/DM Plant; 10.0 KLD is from Scrubber; 40.0 KLD is from Domestic section.

iii The high TDS and low TDS effluents generated from the process are to be separated and treated separately. The high TDS effluents generated from process, washings & Scrubber shall be disposed into stripper followed by MEE and ATFD. The high TDS effluents generated from Pre-treatment of water in RO/DM Plant shall be disposed to MEE followed by ATFD. The condensate shall be reused in cooling towers after necessary treatment. The LTDS effluents shall be treated in an ETP followed by RO system. The permeate is to be re-used in the plant and rejects are to be sent to MEE system. The treated effluents shall be recycled completely. The project proponent shall achieve **Zero Liquid Discharge** and in no case the effluent shall be discharged outside the factory premises. The sewage generated is to treated in an Sewage Treatment Plant (STP) and the treated waste water shall be reused for gardening. The volatile organics shall be sent to recyclers authorized by TSPCB.

iv The proponent shall provide separate storm water drains and harvest the rainwater from the rooftops to recharge the ground water.

v Automatic / online monitoring system (24 x 7 monitoring devices) for flow measurement and relevant pollutants in the treatment system to be installed. The data to be made available to the respective SPCB and in the Industry's website.

vi The industry shall install IP Camera with PAN, TILT Zoom, 5x or above focal length, with night vision capability and flow meters in the channel / drain provided for carrying the effluent from within the premises of the unit.

c) Solid Waste :

i. Hazardous waste generated from the industry such as waste oils, used oils etc., shall be disposed as per the Hazardous Wastes (Management, Handling, and Transboundary movement) Rules, 2008 and its amendments thereof to the recyclers authorized by TSPCB.

ii. 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.

iii. The proponent shall comply with the following w.r.t. solid waste generated after expansion:

S.No	Description	Quantity	Mode of Disposal
1.	Solvent residue	9.43 TPD	Sent to TDSF / Cement Plants for Co-incineration.
2.	Process Organic residue	4.36 TPD	
3.	Stripper Distillate	9.0 KLD	
4.	Spent Carbon	0.54 TPD	
5.	Inorganic residue	0.89 TPD	Sent to TSDF
6.	Hyflow	50.0 Kg/day	
7.	Evaporation salts	5.65 TPD	
8.	ETP Sludge	3.2 TPD	
9.	STP Sludge	2.0 Kg/day	Used as manure / Sent to TSDF
10.	Spent Solvents	170.96 KLD	Recovered within the plant premises.
11.	Spent Mixed Solvents (Non-recoverable)	73.27 KLD	Sent to authorized recovery units/ Cement plants for co-incineration
12.	Ash from Boiler	27.6 TPD	Sold to Brick manufactures
13.	Detoxified containers	18,000 No/Annum	Sold to authorized vendors
14.	Waste oil	1500 LPM	Sent to Authorized Recyclers
15.	Used batteries	60 No/Annum	

B. General Conditions:

i. **This order is valid for a period of 7 years.**

ii. "Consent for Establishment" shall be obtained from Telangana State Pollution Control Board under Air and Water Act before the start of any activity / construction work at site.

iii. This order is issued subject to outcome of the cases (if any), pending in the National Green Tribunal, Southern Zone, Chennai or in any other court.

iv. Provision shall be made for the housing of the construction labour within the site with all necessary infrastructure and facilities such as safe drinking water, fuel for cooking, mobile toilets, mobile STP, medical health care, crèche etc., The housing may be in the form of temporary structures to be removed after the completion of the project. The safe disposal of wastewater and solid wastes generated during the construction phase should be ensured.

v. No change in the process technology and scope of working should be made without prior approval of the SEIAA, TS. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA, TS/ MoEF&CC, GoI, New Delhi, as applicable.

vi. The proponent shall submit half-yearly compliance reports in respect of the terms and conditions stipulated in this order in hard and soft copies to the SEIAA; and CCF, Regional office of MoEF&CC, GoI, Chennai on 1st June and 1st December of each calendar year.

vii. Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone for RSPM, SPM, PM_{10}, $PM_{2.5}$, SO2, NOx monitoring. Location of the stations should be decided based on the meteorological data, topographical features and environmentally and ecologically sensitive targets and frequency of monitoring should be undertaken in consultation with the State Pollution Control Board.

viii. Data on ambient air quality (RPM, SPM, PM_{10}, $PM_{2.5}$, SO_2, NOx) should be regularly submitted to the Ministry including its Regional Office located at Chennai and the State Pollution Control Board/ Central Pollution Control Board once in six months.

ix. Usage of Personnel Protection Equipments by all employees / workers shall be ensured.

x. 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.

xi. Occupational health surveillance program of the workers should be undertaken periodically to observe any contractions due to exposure to dust and take corrective measures, if needed.

xii. The Industry 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.

xiii. A separate environmental management cell with suitable qualified personnel should be set-up under the control of a Senior Executive, who will report directly to the Head of the Organization.

xiv. The funds earmarked for environmental protection measures (capital cost of Rs. 225 Lakhs and recurring cost of Rs. 1632 Lakhs per annum) & also the funds earmarked for Corporate Social Responsibility (CSR) activities, should be kept in separate account and should not be diverted for other purpose. Year wise expenditure should be reported to the SEIAA, Ministry and its Regional Office located at Chennai.

xv. Officials from the Regional Office of MoEF&CC, GoI, Chennai who would be monitoring the compliance of the stipulated conditions and implementation of environmental safeguards should be given full co-operation, facilities and documents/data by the project proponents during their inspection. A complete set of all the documents shall be submitted to the CCF, Regional Office to MoEF&CC, GoI, Chennai.

xvi. The project proponent shall submit the copies of the environmental clearance to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.

xvii The project authorities should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the clearance letter informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with the State Pollution Control Board and SEIAA, Telangana. This order shall be displayed in the website of the project proponent.

xviii Any appeal against this Environmental Clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

xix. The company shall undertake eco-development measures including community welfare measures in the project area.

xx. The proponent shall obtain all other mandatory clearances from respective departments.

xxi. Concealing the factual data or failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.

xxii. The SEIAA may revoke or suspend the order, if implementation of any of the above conditions is not satisfactory. The SEIAA reserves the right to alter/modify the above conditions or stipulate any further condition in the interest of environment protection.

xxiii 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 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

Sd/-	Sd/-	Sd/-
MEMBER SECRETARY	**MEMBER**	**CHAIRMAN,**
SEIAA, T.S.	**SEIAA, T.S.**	**SEIAA, T.S.**

To

Sri C. Mohan Reddy, Director – Operations,
M/s. Hetero Labs Ltd., Unit-I,
Sy.No. 10 (P), Gaddapotharam (V),
Jinnaram (M), Medak District – 502 319
Ph. No. 08458 -277106
E-mail: mohanreddy.c@heterodrugs.com, contact@heterodrugs.com

//T.C.F.B.O//

SENIOR ENVIRONMENTAL ENGINEER
(Unit Head – III)