

J-11011/301/2015-IA II (I)
Government of India
Ministry of Environment, Forest and Climate Change
(I.A. Division)

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Dated: 5th March, 2016

To,
Shri P. Vijaya Kumar Reddy
Director
Plot no. 3, 4 & 5, First Cross, Anrich Industrial Estate,
IDA Bollaram, Medak, Telangana

Email.: svlabspltd@gmail.com ; Fax.: 040-64565626

Subject: Expansion of Bulk Drugs and Intermediates Manufacturing Unit (From 10.5 TPM to 152 TPM) at Sy.No. 501, 506 and 507, Village Koyalagudem, Mandal Choutuppal, District Nalgonda, Telangana by M/s S.V. Labs Pvt. Ltd.- reg. TOR

Ref. No.: Your Proposal no. IA/GJ/IND2/33232/2015; dated 25th November, 2015

Sir,

Kindly refer your proposal no. IA/GJ/IND2/33232/2015 dated 25th November, 2015 along with project documents including Form-I, Pre-feasibility Report and draft 'Terms of Reference' as per the EIA Notification, 2006. It is noted that the proposal is for expansion of bulk drugs and intermediates manufacturing unit (From 10.5 TPM to 152 TPM) at Sy.No. 501, 506 and 507, Village Koyalagudem, Mandal Choutuppal, District Nalgonda, Telangana by M/s S.V. Labs Pvt. Ltd. Following products will be manufactured after proposed expansion:

S. No	Name of the Product	Capacity	
		Kg/day	TPM
1	Cetirizine Dihydrochloride	100	3.0
2	Carvedilol	100	3.0
3	Terbinafine Hydrochloride	100	3.0
4	Omeprazole	100	3.0
5	Fluconazole	100	3.0
6	Cis-Bromo Benzoate	200	6.0
7	4 Amino-1-Methyl-3n-Propyl Pyrazole5- Carboxamide	83	2.5
8	Trityl Tetrazole Bromomethyl Biphenyl	300	9.0
9	Thionordiazepam	50	1.5
10	Tetralone	1500	45
11	Citalopram Hydrobromide	150	4.5
12	Losartan Potassium	150	4.5
13	CBX	100	3.0
14	SSB	300	9.0
15	2-Acetyl Thiophene	100	3.0
16	Bosentan	100	3.0
17	Dapagliflozin propanediol	100	3.0
18	Ponatinib	100	3.0

19	Pozaconazole	35	1.1
20	Vidagliptin	35	1.1
21	Abacavir Sulfate(CHN)	35	1.1
22	Sumatriptan(KSM)	100	3.0
23	Amlodipine Maleate	100	3.0
24	4-BBFA	200	3.0
25	Ezetimibe-1	100	3.0
26	Methyl 2- (2-Chlorophenyl) Aceetate	700	21.0
27	Trityl Chloride	1000	30.0
28	Atorvatatin Calcium	100	3.0
29	Pregabalin	100	3.0
30	Rosuvastatin Clacium	100	3.0
31	Rabeprazole Sodium	30	0.9
32	Sildenafil Citrate	100	3.0
33	Quetiapine Fumerate	100	3.0
34	Darunavir Ethanolate	350	10.5
	Total (Worst Case 12 Products)	5050	152

List of By product

Name of bye product	Name of product	Capacity	
		Kg/day	TPM
Aluminum Hydroxide Solution (6.4%)	Tetralone	6632.2	198.9
Hydrochloric Acid (35%)		1534	46

2.0 Draft Terms of Reference (TOR) have been discussed and finalized during 3rd Expert Appraisal Committee (Industry-2) meeting held during 18th-19th January, 2015 for preparation of EIA/EMP report. The Committee prescribed the following Specific and Additional TOR in addition to Generic TOR provided at Annexure-I (refer to Ministry's website) for preparation of EIA-EMP report:

A. Standard TOR

1. Details on solvents to be used, measures for solvent recovery and for emissions control.
2. Details of process emissions from the proposed unit and its arrangement to control.
3. Ambient air quality data should include VOC, other process-specific pollutants* like NH₃*, chlorine*, HCl*, HBr*, H₂S*, HF*, etc., (* - as applicable)
4. Work zone monitoring arrangements for hazardous chemicals.
5. Detailed effluent treatment scheme including ssegregation of effluent streams for units adopting 'Zero' liquid discharge.
6. Action plan for odour control to be submitted.
7. A copy of the Memorandum of Understanding signed with cement manufacturers indicating clearly that they co-process organic solid/hazardous waste generated.
8. Authorization/Membership for the disposal of liquid effluent in CETP and solid/hazardous waste in TSDF, if any.
9. Action plan for utilization of MEE/dryers salts.
10. Material Safety Data Sheet for all the Chemicals are being used/will be used.
11. Authorization/Membership for the disposal of solid/hazardous waste in TSDF.
12. Details of incinerator if to be installed.
13. Risk assessment for storage and handling of hazardous chemicals/solvents. Action plan for handling & safety system to be incorporated.

14. Arrangements for ensuring health and safety of workers engaged in handling of toxic materials.

B. Additional TOR

- i. Public hearing to be conducted and issues raised and commitments made by the project proponent on the same should be included in EIA/EMP Report in the form of tabular chart with financial budget for complying with the commitments made.
- ii. A Copy of certified compliance report to the environmental conditions prescribed in the existing EC. Action taken report/ detailed action plan on the partly/non-compliance conditions reported by the MoEF&CC Regional Office.
- iii. ZLD system to be adopted with reuse-recycling of wastewater.

3.0 These 'TORs' should be considered for the preparation of EIA/EMP for expansion of bulk drugs and intermediates manufacturing unit (From 10.5 TPM to 152 TPM) at Sy.No. 501, 506 and 507, Village Koyalagudem, Mandal Choutuppal, District Nalgonda, Telangana by M/s S.V. Labs Pvt. Ltd. in addition to all the relevant information as per the 'General Structure of EIA' given in Appendix III and IIIA in the EIA Notification, 2006. The EIA/EMP as per TORs should be submitted to the Chairman, Telangana Pollution Control Board, for public consultation. The SPCB shall conduct the public hearing/public consultation as per the provisions of EIA notification, 2006.

4.0 You are requested to kindly submit the final EIA/EMP prepared as per TORs and incorporating all the issues raised during Public Hearing / Public Consultation to the Ministry for considering the proposal for environmental clearance ***within 3 years as per the MoEF O.M. No. J-11013/41/2006-IA.II (I) dated 8th October, 2014.***

5.0 The consultants involved in the preparation of EIA/EMP report after accreditation with Quality Council of India/ National Accreditation Board of Education and Training (QCI/NABET) would need to include a certificate in this regard in the EIA/EMP reports prepared by them and data provided by other Organization(s)/Laboratories including their status of approvals etc.



(Lalit Bokolia)
Additional Director

Copy to:

- 1 A-3, Paryavaran Bhavan, Sanath Nagar Rd, Sanath Nagar Industrial Estate, Sanath Nagar, Hyderabad, Telangana 500018.
- 2 Additional Principal Chief Conservator of Forests (C), Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1st and 11nd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, Chennai – 34



(Lalit Bokolia)
Additional Director

