

F. No. J-11011/57/2016-IA.II (I)
Government of India
Ministry of Environment, Forest and Climate Change
(Impact Assessment Division)

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Dated: 08th June, 2017

To,

The Director
(Shri K. V. Bhaskar)
M/s Dasami Lab Pvt. Ltd.,
Village Veliminedu, Chityal Mandal,
District Nalgonda, Telangana

Sub: Expansion of Bulk Drugs and Intermediates Manufacturing Unit (421 TPM) at Sy. No. 404,405, 407, 408,409 & 410, Village Veliminedu, Chityal Mandal, District Nalgonda, Telangana by M/s Dasami Lab Pvt. Ltd. - Terms of Reference - reg.

Ref: Online Proposal No. IA/TG/IND2/42432/2016 dated 27th January, 2016.

Sir,

This has reference to your online proposal no. IA/TG/IND2/42432/2016 dated 27th January, 2016, submitting along with project documents including Form I, draft Terms of References and Pre-feasibility Report (PFR) regarding the above mentioned project.

2. It is noted that the proposal is for Terms of Reference for Expansion of Bulk Drugs and Intermediates Manufacturing Unit (421 TPM) at Sy. No. 404, 405, 407, 408, 409 & 410, Village Veliminedu, Chityal Mandal, District Nalgonda, Telangana by M/s Dasami Lab Pvt. Ltd.

3. As per Form 1 and PFR, the total plot area after expansion is 51 acres out of which 18 acres of land will be developed as green belt. Total project cost is ₹ 45 crore. About 560 persons will be employed in this proposed expansion project. It is reported that no national parks, wildlife sanctuaries, Protected Forests (PF), Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc. lies within 10 km distance. There are two Reserve Forests in the study area; Chityala RF at a distance of 6 Km in east direction, Shivanenigudem RF at a distance of 9 Km in NE direction of the site.

4. It is informed that the total water requirement after expansion is in the order of 487.2 m³/day consisting of 292.2 m³/day of freshwater and the remaining is recycled water. Capacity of the existing Coal fired boiler is 5 TPH and proposed coal fired boilers will be 2 x 10 TPH, provided with bagfilter as APCS. Backup DG sets of 3X1000 KVA has been proposed in addition to existing DG sets of 1x 380 KVA to cater to energy requirement during load shut down. DG sets shall be provided with stack of adequate height.

5. It is informed that the Ministry has issued Environmental Clearance vide letter no. F. No. J-11011/533/2007-IA.II (I), dated 21.02.2008 to M/s SVAKRM Laboratories (Pvt.) Ltd. and the PP proposed to expand the same project. The PP has obtained CTO dated 29.03.2016 in the name of M/s Dasami Lab Pvt. Ltd.

6. All Synthetic Organic Chemicals Industry located outside the notified industrial area/estate are listed at S.N. 5(f) of Schedule of Environmental Impact Assessment (EIA) Notification under Category 'A' and is appraised at Central Level by Expert Appraisal Committee (EAC).

7. The existing and proposed product along with capacity are:

Existing product as per EC:

S. No	Name of the Product	Capacity (TPA)
1.	Tramadol Hydrochloride	60.0
2.	Ramipril	60.0
3.	Omeprazole	60.0
4.	Carvedilol	60.0
5.	Setrelina Hydrochloride	60.0
6.	Duloxetine Hydrochloride	36.0
7.	Sparfloxacin	48.0
8.	Drotaverine Hydrochloride	30.0
9.	Clopidogrel Hydrogen Bisulfate	60.0
b.	By- product	
10.	Spent Sulphuric acid	364.8

Proposed products

S. No.	Name of the Product	Capacity	
		TPM	TPD
1	Amlodipine Besylate	20	0.67
2	Aprimilast	3	0.10
3	Bocepravir	6	0.20
4	Bupropion HCl	20	0.67
5	Carvedilol	30	1.00
6	Clopidogrel Hydrogen Bisulfate	10	0.33
7	Colisevelam	6	0.20
8	Dalfampridine	17	0.57
9	Dex lansoprazole	5	0.17
10	Divalproex Sodium	15	0.50
11	Drotaverine HCl	3	0.10
12	Duloxetine HCl	15	0.50
13	Esli Carbazapine	2	0.07
14	Fexofenadine HCl	10	0.33
15	Glimepride	3	0.10
16	Lansoprazole	8	0.27
17	Lomitapide	2	0.07
18	Mesalamine	7	0.23
19	Nebumitane	10	0.33
20	Omeprazole	5	0.17

21	Piperquine Phosphate	5	0.17
22	posacanazole	7	0.23
23	Ramipril	7	0.23
24	Ranolazine	10	0.33
25	Sevelamir HCl	29	0.97
26	Sparfloxacin	20	0.67
27	Telaprevir	5	0.17
28	Ticagrelor	1	0.03
29	Tramadol HCl	12	0.40
30	Valacyclovir	6	0.20
31	Valagancyclovir HCl	2	0.07
32	Abiraterone Acetate	1	0.03
33	Anastrozole	2	0.07
34	Bendamustine Hydrochloride	2.5	0.08
35	Bexarotene	3	0.10
36	Bicalutamide	5	0.17
37	Bortezomib	0.5	0.02
38	Carboplatin	5	0.17
39	Capecitabine	2	0.07
40	Cisplatin	2	0.07
41	Cyclophosphamide	2	0.07
42	Dasatinib	2	0.07
43	Emtricitabine	30	1.00
44	Erlotinib HCl	4	0.13
45	Gefitinib	2	0.07
46	Gemcitabine HCl	1	0.03
47	Imatinib Mesylate	16	0.53
48	Irinotecan HCl	14	0.47
49	Lapatinib Ditosylate Monohydrate	2	0.07
50	Letrozole	2.5	0.08
51	Nilotinib HCl	2	0.07
52	Oxaliplatin	4	0.13
53	Pazopanib Hydrochloride	2	0.07
54	Pemetrexed Disodium	0.5	0.02
55	Sorafenib Tosylate	6	0.20
56	Temozolomide	1	0.03
57	Sunitinib Malate	6	0.20
	Total (Worst Case-27 Products)	421	11.57

8. The project proposal and Draft Terms of Reference (TOR) was considered by the Expert Appraisal Committee (Industry -2) in its 6th EAC held during 30th March, 2016- 2nd April, 2016 and 20th EAC meeting held during 27th -28th February, 2017. The Committee prescribed the following **Additional TOR with public hearing along with Standard TOR** as available in the Ministry website for preparation of EIA-EMP report:

Additional TOR

- 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. Existing EC need to be transferred in the name of M/s Dasami Lab Pvt. Ltd.
- iv. Proposed expansion including chemical storage should to be undertaken within the existing plot area without affecting nearby agricultural land. Adequate safety measure to be adopted without affecting nearby farmer's land.
- v. Green belt shall be developed with at least 9m width in the periphery with perennial trees like neem, seasm, teak etc.

9. The request of the PP for transfer of existing Environmental Clearance in the name of M/s Dasami Lab Pvt. Ltd. would be considered after the receipt of the Certified Compliance Report from the Regional Office of the Ministry.


10. These **'TORs along with Public hearing'** should be considered for the preparation of EIA/EMP for the above referred project, 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. Public hearing has to be conducted as per the provisions of the EIA Notification, 2006. The draft EIA/EMP report shall be submitted to the State Pollution Control Board for public hearing. The issues emerged and response to the issues shall be incorporated in the final EIA report.

11. 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.


8.6.2017
(Yogendra Pal Singh)
Scientist 'D'

Copy to:-

1. The Chairman, Telangana State Pollution Control Board, Plot No. A 3, Paryavaran Bhawan, Sanath Nagar, Hyderabad – 500 018, Telangana.
2. The Additional Principal Chief Conservator of Forests (C), Ministry of Environment, Forest and Climate Change, Regional Office (SEZ), 1st and IInd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, Chennai – 600 034
3. Guard File/Monitoring File/Website/Record File.


8.6.2017
(Yogendra Pal Singh)
Scientist 'D'