

F. No. IA-J-11011/326/2016-IA-II(I)
Government of India
Ministry of Environment, Forest and Climate Change
(IA-II Section)

Indira Paryavaran Bhawan
Jorbagh Road, New Delhi - 3

Dated: 19th November, 2018

To

M/s Strides Shasun Limited
Plot No.A-1/B, SIPCOT Industrial Complex
Village Kudikadu, District Cuddalore (Tamil Nadu)

Sub: Expansion of Bulk Drugs Manufacturing Unit by M/s Strides Shasun Limited at Plot No.A-1/A, A-1/B, A-1/C, A-2/B, A-2/C, A-2/D, C8-3/C, C8- 3/ A, C-7/2, SIPCOT Industrial Complex, Village Kudikadu, District Cuddalore (Tamil Nadu) - Environmental Clearance - reg.

Sir,

This has reference to your proposal No. IA/TN/IND2/58794/2016 dated 6th September 2018, submitting the EIA/EMP report on the above subject matter.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for environmental clearance to the project for expansion of bulk drugs manufacturing unit from the present capacity of 3376.40 TPA (53 Products) to 5783.84 TPA (77 Products) by M/s Strides Shasun Limited in an area of 78156.94 sqm at Plot No.A-1/A, A-1/B, A-1/C, A-2/B, A-2/C, A-2/D, C8-3/C, C8- 3/ A, C-7/2, SIPCOT Industrial Complex, Village Kudikadu, District Cuddalore (Tamil Nadu).

3. The details of products are as under :-

S. No	Product	Existing	Additional	Total
		Capacity (TPA)		
1	Allyl Isopropyl urea	0	5	5
2	Aloiglipstone	1	-1	0
3	Apreptant	1	1	2
4	Atorvastatin	0	5	5
5	Azelaic acid	0	1	1
6	Benzarone	2	8	10
7	BepotastineBesilate	0	3	3
8	Blonanserine	0	0.5	0.5
9	Carisoprodol	40	0	40
10	CD-6051(A-49)	10	-10	0
11	Cebrazalone	0	5	5
12	Celecoxib	20	10	30
13	Chlorophenesin	144	-139	5
14	Cinacalcet Hydrochloride	1	0	1
15	CKE	36	-32	4



16	ClopidogrelBisulphite	1.2	-1.2	0
17	ClopidogrelNapsylate	1.2	-1.2	0
18	Cobicistat	0	12	12
19	Colesevelam	50	100	150
20	Cycloserine	2	18	20
21	DabigatranEtexilateMesylate	3	-1	2
22	Dexlansoprazole	1	0	1
23	Dextropolisterix	0	10	10
24	DextromethorphanHBr	10	30	40
25	DimethylFumarate	0	2	2
26	Doxycycline	2	-2	0
27	Effavirenz	0	30	30
28	Elvitegravire	0	12	12
29	Emtricitabine	0	30	30
30	EsomeprazoleMagnesium	0	10	10
31	Flurbiprofen/SFlurbiprofen	0	30	30
32	Gabapentine and its intermediates	150	850	1000
33	Ibu and Intermediate Aldehyde	1700	1225	2925
34	Ibulysinate	0	20	20
35	Ibuprofen	400	-400	0
36	IbuSodium	50	-30	20
37	Imidafenacin	0	2	2
38	Indapamide	10	-9	1
39	Isradipine	1	-0.9	0.1
40	Ketoprofen	24	-18	6
41	Lamvudine	0	1	1
42	LanthanumCarbonate	10	20	30
43	Lanzoprazole	0	1	1
44	Leviteracetam	50	-20	30
45	Loratidine	2	-2	0
46	Loxoprofen	50	-49	1
47	LurasidoneHCl	1	1	2
48	Meprobamate	2	-1	1
49	Methohexital	0	0.54	0.54
50	Methylthioniniumchloride	250	-250	0
51	MilnacipranHCl	0	1	1
52	Mirabegron	0	5	5
53	Montelukas Sodium	1	-1	0
54	Moxifloxacin	5	-5	0
55	Nabumetone	10	62	72
56	Nevarapine	0	1	1

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57	Nizatidine	6	18	24
58	Olanzapine	1	0	1
59	Olmestartat	1	-1	0
60	PantaprazoleSodium	10	-9	1
61	PentosanPolysulfate	0	1	1
62	Phexphynadine	25	-25	0
63	Pindolol	0	2	2
64	Pitavastatin	1	-0.8	0.2
65	Posaconazole	0	5	5
66	Pregabalin	50	10	60
67	QuinaprilHydrochloride	0	1	1
68	RantidineHClFormII	50	370	420
69	Rebamipide	0	50	50
70	Ridanehydrobromide	0	10	10
71	Rifaximin	0	3	3
72	Rivaroxaban	1	4	5
73	Roflumilast	1	0	1
74	Rosigiltazone	1	-1	0
75	Rosuvastatin Calcium	1	9	10
76	S+ IbuProfen	0	20	20
77	SapropterinHCl	1	-0.5	0.5
78	SevHCl	40	-16	24
79	Sev carbonate	50	100	150
80	Sofosbovir	0	12	12
81	SumatriptanSuccinate	2	-2	0
82	TAF	0	60	60
83	Tenofovir	10	140	150
84	Terizidone	0	3	3
85	Ticagrelor	0	5	5
86	Ursodiol	0	6	6
87	Valacyclovir	0	12	12
88	Venlafaxine HCl	60	-20	40
89	VilazadoneHCl	0	5	5
90	VX-950	24	-24	0
91	Zidovidine	0	120	120
92	Zileuton	0	2	2
Total		3376.4	2407.44	5783.84

4. The proposed expansion requires additional area of 5260.92 sqm, making the total land area available for the project as 78156.94 sqm. Industry has developed green belt in an area of 25839.216 sqm, and thus covering 33% of total area of the project. The estimated project cost for the proposed expansion is Rs.75 crores. Total capital cost earmarked towards environmental pollution control measures is Rs.18.31 crores and the recurring cost (operation and maintenance) will be about Rs.7.37 crores per annum. Total employment will be for 525 persons as direct and 175 persons as indirect after expansion.

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5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc. within 10 km from the project site. Uppanar, Gadilam rivers are flowing within 10 km distance from the project site.

6. Total water requirement is estimated to be 1123 cum/day, of which fresh water requirement is 610 cum/day proposed to be met from SIPCOT water supply. Process effluent of 570 cum/day will be treated through ETP. There will be no discharge of treated/untreated waste water from the unit, and thus ensuring Zero Liquid Discharge. Treated water from STP will be used for green belt.

Power requirement after expansion will be 5500 kVA including existing requirement of 4500 kVA, proposed to be met from Tamil Nadu Generation and Distribution Corporation Limited. Existing unit has 4 DG sets (2 x 1000 kVA & 2 x 1500 kVA), additionally 1x 1500 kVA and 1 x 1000 kVA capacity DG Sets will be used as standby during power failure. Stack (height - 20m) will be provided as per CPCB norms to the proposed DG sets.

Existing unit has bio-briquette fired boilers of capacity, 6 TPH, 10 TPH and 12 TPH, additionally one bio-briquette fired boiler of 16 TPH capacity will be installed. Bag filter with a stack of height of 42 m will be installed to control the particulate emissions within the statutory norms for the proposed boilers.

7. The project/activities are covered under category B of item 5(f) 'Synthetic organic chemicals industry' of the Schedule to the Environment Impact Assessment Notification, 2006, and requires appraisal at State level. However, in view of the NGT order dated 1st August, 2016 in Appeal No.123 of 2016 (SZ)(THC) in the matter of 'Puduchery Environment Protection Association Vs Union of India & others' and due to non-existence of SEIAA in the State of Tamil Nadu for the present, the project was appraised at Central Level by the sectoral Expert Appraisal Committee (EAC) in the Ministry.

8. The terms of reference (ToR) for the project was granted on 29th April, 2017. Public hearing was exempted as per the provision contained in para 7 (i) III Stage (3)(i)(b) of the EIA Notification, 2006.

9. The proposal for environmental clearance was considered by the EAC (Industry-2) in its meeting held on 24-26 September, 2018. The project proponent and their consultant M/s Hubert Enviro Care Systems (P) Ltd presented the EIA/EMP report. The Committee found the EIA/EMP report complying with the terms and conditions of the ToR, and recommended the proposal for environmental clearance to the project with certain conditions.

10. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), the Ministry of Environment, Forest and Climate Change hereby accords environmental clearance to the project for **Expansion of Bulk Drugs Manufacturing Unit from the present capacity of 3376.40 TPA (53 Products) to 5783.84 TPA (77 Products) by M/s Strides Shasun Limited** at Plot No.A-1/A, A-1/B, A-1/C, A-2/B, A-2/C, A-2/D, C8-3/C, C8- 3/ A, C-7/2, SIPCOT Industrial Complex, Village Kudikadu, District Cuddalore (Tamil Nadu), under the provisions of the EIA Notification, 2006, read with subsequent amendments therein, subject to compliance of the terms and conditions as environmental safeguards, as under:-

- (i) Consent to Establish/Operate for the project shall be obtained from the State Pollution Control Board as required under the Air (Prevention and Control of Pollution) Act, 1981 and the Water (Prevention and Control of Pollution) Act, 1974.



- (ii) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
- (iii) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.
- (iv) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended from time to time shall be followed.
- (v) Bio-briquette shall be used as fuel in the boiler in any case, Coal/lignite shall not be used as fuel in the boiler. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
- (vi) Solvent management shall be carried out as follows:
 - (a) Reactor shall be connected to chilled brine condenser system.
 - (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - (c) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - (d) Solvents shall be stored in a separate space specified with all safety measures.
 - (e) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - (f) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - (g) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (vii) Total fresh water requirement shall not exceed 610 cum/day to be met from SIPCOT water supply. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (viii) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- (ix) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (x) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- (xi) 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.



- (xii) Fly ash should be stored separately as per CPCB guidelines so that it should 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 should be avoided.
- (xiii) The company shall undertake waste minimization measures as below:-
 - (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.
- (xiv) The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (xv) At least 1% of the total project cost shall be allocated for Corporate Environment Responsibility (CER) and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (xvi) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- (xvii) 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.
- (xviii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (xix) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

10.1. The grant of environmental clearance is subject to compliance of other general conditions, as under:-

- (i) The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board, Central Pollution Control Board, State Government and any other statutory authority.
- (ii) No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. 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 each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (iv) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be followed.
- (v) 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).
- (vi) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and to utilize the same for process requirements.
- (vii) 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.
- (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, and risk mitigation measures 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. CER 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) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change 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.
- (xii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad/Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.
- (xiii) 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&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.




- (xiv) 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&CC by e-mail.
- (xv) 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://moef.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.
- (xvi) 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.

11. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.


19/11/2018
(S. K. Srivastava)
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Copy to: -

1. The Additional PCCF (C), MoEF&CC, Regional Office (SEZ), 1st and 11nd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, Chennai - 34
2. The Secretary, Department of Environment, Government of Tamil Nadu, No.1, Jeenis Road, Panagal Building, Ground Floor, Saidapet, Chennai- 15 (Tamilnadu)
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex East Arjun Nagar, Delhi - 32
4. The Member Secretary, Tamil Nadu State Pollution Control Board, Chennai (Tamil Nadu)
5. Guard File/Monitoring File/Website/Record File


19/11/2018
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