

F. No. J-11011/316/2016-IA-II(I)
Government of India
Ministry of Environment, Forest and Climate Change
(Impact Assessment Division)

Indira Paryavaran Bhawan
Jorbagh Road, New Delhi -3

Dated: 01st August, 2017

To ✓

M/s Divi's Laboratories Limited (Unit-2)
Chippada Village, Annavaram Post
Bheemunipatnam Mandal, Visakhapatnam
(Andhra Pradesh)-531 162

Sub: Modernization of the Bulk Drug Unit at Sy No. 52, 134, 138, 139, 140, 159, 160 to 168, 168/1, 183 & 184 of Chippada village and 1 to 4, 6, 45 & 46 and additional survey number 107, 158, 168, to 172 of Chippada and Annavaram Villages, Annavaram Taluka, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh by M/s Divi's Laboratories Limited (Unit-2) – Environmental Clearance – reg.

Ref: Online Proposal No. IA/AP/IND2/58641/2016 dated 24th April, 2017.

Sir,

This has reference to your online proposal no. IA/AP/IND2/58641/2016 dated 24th April, 2017, along with project documents including form I, terms of references, pre-feasibility report and EIA/EMP report regarding the above mentioned project.

2. The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that the proposal is for modernization of the bulk drug unit at Sy no. 52, 134, 138, 139, 140, 159, 160 to 168, 168/1, 183 & 184 of Chippada village and 1 to 4, 6, 45 & 46 and additional survey number 107, 158, 168, to 172 of Chippada and Annavaram Villages, Annavaram Taluka, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh by M/s Divi's Laboratories Limited (Unit-2). As informed and as per the documents submitted by the project proponent (PP), the existing land area is 387 acres, additional 108.59 acres land will be used for proposed modernization. Industry has already developed greenbelt in an area of more than 33%, that is, 200 acres out of 387 acres of the total area of the project. During the modernization, PP will increase the greenbelt area to 237 acres out of 495.59 Acres. The estimated project cost is Rs 100 crores. Total capital cost earmarked towards environmental pollution control measures is Rs 40 crores and the recurring cost (operation and maintenance) will be about Rs 4 crores per annum. Total employment will be for 7826 persons as direct & also has additional indirect employment after modernization. Industry allocated Rs 7.4 Crores for the current year and for consecutive years as per the existing norms towards corporate social responsibility. It is reported that, no National parks, Wildlife sanctuaries, Biosphere reserves, Tiger / Elephant reserves, Wildlife corridors, etc. lies within 10 km radius. However, Amanam reserve forest in north and Gillman field reserve forest in south are located within 10 km area. Gosthani river is flowing at a distance of 2

km in west direction. Sea cost is at a distance of 1 km from the project site. CRZ clearance is not applicable to the proposed project.

3. All Synthetic Organic Chemicals Industry located outside a 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).

4. The terms of references (ToR) has been issued vide Ministry's letter of even no. dated 22.02.2017. Public Hearing for the proposed modernization project has been exempted under para 7(ii) of EIA Notification, 2006.

5. The proposal for environmental clearance (EC) was placed before the EAC (Industry-2) in its 23rd meeting held during 3-5th May, 2017 and 24th meeting held during 14-16th June, 2017. The project proponent and the accredited consultant M/s Ramky Enviro Services Private Limited, Hyderabad gave a detailed presentation on the salient features of the project and proposed environmental protection measures to be undertaken, as under:-

(a). The existing products and its capacities are:

S.No.	Product Name	Quantity(Kg/day)
1	DL -Naproxen (Intermediates of NAP/ SN) ~1960tons	274.0
2	Naproxen (450MTA)	5616.4
3	Naproxen (Sodium) (1600MTA)	
4	Sigma-I with ISA & ISB (Dextromethorphan HBR Intermediates)	684.9
5	Sigma (Dextromethorphan HBR)	5.5
6	Atipa (Atipadichloride)	684.9
7	Impala with BAH & 3-HAP	479.5
8	F MOC OSU	1.4
9	CPCCA (KEY)	82.2
10	Verapamil HCL	1.4
11	Venlafaxine	41.1
12	Simvastatin	82.2
13	Bupropion HCL	68.5
14	Sitagliptin Phosphate & Ketoamide	411.0
15	Amino Alcohol	1.4
16	Carbidopa	137.0
17	Levodopa	547.9
18	Gabapentin	4383.6
19	Triprolidine HCL	5.5
20	GW 622082 X (Classic)	2.7
21	Lamotrigine	191.8
22	Capecitabine	54.8
23	Vigabatrine	13.7
24	Raltegravier	109.6

25	DCAM	41.1
26	CKE	54.8
27	Orlistat	82.2
28	DIAL	2.7
29	Astaxanthin	137.0
30	Canthaxanthin	13.7
31	Lycopene	27.4
32	Beta-Carotene	137.0
33	Ascorbyl Palmitate	27.4
34	Z-L Valine	191.8
35	Losartan (Mecedes)	274.0
36	Atovaquine (IVAX-new)	68.5
37	Sumatriptan	8.2
38	MOC-Valine	2.7
39	Intermediate of Levetiracetam	821.9
40	BOC-Core Succinate/ BCS (Davincy)	137.0
41	Ketoenamine (RADO)	274.0
42	2,4- Wing Active Ester (Zodiac)	95.9
43	Dihydroxy Pyridone Carboxylic Acid Methyl Ester /DHPM (Elentra)	41.1
44	Alendronic Acid (OPTRA)	27.4
45	Bosentan Monohydrate (LILLY)	13.7
46	Entacapone	13.7
47	Irbesartan	68.5
48	4-Isopropyl-3- Methyl Phenol/ IPMP (Dione)	2.7
49	Valsartan (Chevorlet)	274.0
50	Olmisartan (EPIC)	5.5
51	2,3-Dimethyl-6-Amino-2-H-Indazole /GW776994 (MIMAS)	41.1
52	4-Chloro-6- Methoxy-7(3-Morpholin-4-YL Propoxy) Quinoline/SB2192604A (ERIS)	2.71
53	(2R,3R)-3-(2,5-Difluorophenyl)-3-Hydroxy-2-Methyl-4-(1H-1,2,4-Triazol-1-YL) Butanethioamide /Bal 17697 (Nano)	5.5
54	2-((1,5-BIS (Benzhydroxy)-4-OXO -1,4-Dihydropyridin-2-YL)Methoxy)Isoindoline-1,3-Dione /Bal0029711(Swallow)	5.5
55	3-(Propan-2-YL)-5-(Trichloromethyl)-1,2,4-Oxadiazole (GSK 2116107 A)	2.7
56	GSK 2226529A	2.7
57	(1S)-2-Amino-1-{3-[3-(Benzyloxy)Propoxy]Phenyl}Ethanol Hydrochloride (GSK 2395558B)	2.7
58	Apocarotenol	5.5

59	Lufein	5.5
60	Levodopa Ethylester Succinate	2.7
61	Intermediate of Preladenant	2.7
62	Phthalazinone	2.7
63	5-Bromo-[1,2,4] Triazol [1,5-A]Pyridine-2-YL Amine (GSK 283119A)	2.7
64	Enoxaparin Sodium	2.7
65	EF-9 [3-O-Acetyl-1,6-Anhydro-2-Azido-2-Deoxy-4-O-(Methyl 2,3-DI-O-Glucopyranosyluronate) Beta-D-Glucopyranose	2.7
66	Lacosamide	2.7
67	Pregabalin	27.4
68	Chloropurine/CIS(1S,4R)-1-Amino-4-(Hydroxymethyl)-2-Cyclopentene.HCL / Amino Alcohol	205.5
69	Abacavir	2.7
70	Suvorexant HCL (Including Amine HCL & Triazole Acid)	13.7
71	Propan-2-yl(2r)-2-[(r)-({(2r,3r,4r,5r)-4-chloro-5-[2,4-dioxo-3,4-dihydropyrimidin-1(2h)-yl]-3-hydroxy-4-methyloxolan-2yl}methoxy)(phenoxy)phosphoryl]amino}propanoate	13.7
72	Doultegravir	5.5
73	Pantaprozole	2.7
74	Esomeprozole	2.7
75	Allogliptin	2.7
76	Merabagran	2.7
77	Vildagliptin	2.7
78	Linagliptin	2.7
79	Ranolazine	5.5
80	Vilazodone HCL	2.7
81	Piprequine	2.7
82	Sofosbuvir	2.7
83	UBT	5.5
84	TATD Salt	5.5
85	Mesalamine	68.5
86	Ethyl Ester	5.5
87	Ethyl Isocyanato Acetate	2.7
88	R&D Products	109.6

- (b). Ambient air quality monitoring was carried out at 10 locations during December, 2016 - February, 2017. The baseline data indicates the ranges of concentrations as: PM₁₀ (41.6-51.4 µg/m³), PM_{2.5} (21.7 - 29.8 µg/m³), SO₂ (11.9 – 21.2 µg/m³) and NO_x (18.1 – 29.1 µg/m³). AAQ modeling study for point source emissions indicates that the maximum incremental GLCs from the existing project would be

4.1µg/m³, 8.1µg/m³ and 19.9µg/m³ with respect to PM₁₀, SO₂ and NO_x. The resultant concentrations are within the National Ambient Air Quality Standards (NAAQS).

- (c). Total water requirement is 1866.6 m³/day of which fresh water requirement of 1466.6m³/day and will be met from Gosthani river.
- (d). Total effluent of 1448.7m³/day will be treated through effluent treatment plant/sewage treatment plant and 600 m³/day treated water will be used for greenbelt and remaining 814 m³/day of treated water will be disposed to sea after meeting the marine discharge standards.
- (e). Power requirement is 30 MVA will be met from AP Transco. Existing unit has DG sets of 6x1500 kVA, 6x1250 kVA, 2x1000 kVA, 2x320 kVA, 2x125 kVA, 1x62.5 kVA and 1x10 kVA capacities are used as stand by during power failure. Stack heights are provided as per the CPCB norms of DG sets.
- (f). Existing unit has 24 TPH/16 TPH/6 TPH coal fired boilers with ESP/bag filter/multi cyclone separator with a stack of height of 35/35/30 m for controlling the Particulate emissions (within statutory limit of 115mg/Nm³) respectively. The process emissions of NH₃, SO₂, CO, HCl, H₂S, CO₂, H₂ etc., are generated. The process emissions resulting from the production of various products such as carbon monoxide, carbon dioxide & hydrogen are left into atmosphere where as other process emissions are scrubbed with respective absorbing solutions (water, alkali/acid) and the scrubbed effluent is sent to ETP for treatment and disposal.
- (g). Details of solid waste from manufacturing process and its management measures are as below:-

1. Details of the Process Salts

S.No	Salts Description	Source of generation	Quantity (kg/day)	Method of Disposal
1	KCl / K ₂ SO ₄	Process	280.21	Sold to outside parties as by products
2	NaSO ₄	Process	1097.42	
3	Sodium Acetate	Process	268.37	
4	Wet Iron Sludge	Process	135.4	

2. Solid & Hazardous waste generation and disposal methods

S.No	Waste generation	Quantity	Method of Disposal
1	Process residue	3102 kg/ Day	Will be sent to authorized cement plants for co-processing or for incineration at onsite / TSDF Parawada, Visakhapatnam District.
2	ETP Sludge	200 kg/ Day	To TSDF, Parawada, Visakhapatnam District for secured land filling.
3	Multiple effect evaporation or forced evaporation salts	391 kg/ Day	
4	Incinerated ash	75 kg/ Day	

5	Containers & Container liners of Hazardous chemicals & hazardous Wastes.	Containers 2000 no's/month and Liners 5000 kg's/month	After detoxification, it shall be disposed to the outside agencies.
6	Spent Carbon	250 kg/ day	Shall be used if required in filtration or Shall be sent to the authorize cement plants for co-processing. Hence there is no impact on Environment
7	Used oil/Waste lubricant oil.	200 Ltrs/ Month	Sent to authorized re-processors/recyclers.
8	Spent Solvents	258.7 kL / Day	Shall be recovered within the premises.
9	Mixed spent Solvent	80 kL / Day	Sent to authorized agencies/Co-incineration in cement industries
10	Spent acids	35 kL/ Day	Sent to authorized agencies
11	Spent Catalysts	2000 kg/ Month	Sent to authorized re-processors/recyclers.

- (h). It is reported that, the modernization of the project will be carried out in two phases. It will add 108.59 Acres (43.94 Ha) of land to existing 387 Acres (156.6 ha) land for decongestion of the production area, ETP area, Storage area, etc. by shifting non production activities to new area. In Phase-1, works include construction of production blocks & ancillary works; production related utilities and others in Phase-2. Total area after modernization is 495.59 acres (200.54 ha).
- (i). In Phase-1, the non production facility are envisaged in extended areas are modern ETP on elevated structure, 24-ton Coal fired boiler, coal and ash storage, waste yard & non-moving ware house (engg& others), fresh water reservoir, treated water disposal, all utilities for above like air system for ETP, water treatment plant, transformer, fire fighting system for hazardous storage, coal sheds associated facilities etc. In Phase-2, production facilities including construction of production blocks & ancillary works, production related utilities and others with a green belt of around 30 acres will be made.
- (j). It is reported that, the proposal is to meet global manufacturing practices in pharma sector by adopting all modern facilities for compliances to continue to achieve the export targets. During the proposed modernization there will not be any change in production capacity, number of products, water consumption, wastewater generation, pollution loads.
- (k). Ministry had issued environmental clearance vide letter no. J-11011/418/2006-IA.II (I) dated 10.10.2007 for Bulk Drug unit (change in product mix in the existing unit) to M/s. Divi's Laboratories Limited. The PP has submitted the copy of the certified compliance report of the existing EC, issued by Ministry's Regional office at Chennai vide letter no. EP/12.1/864&235/AP dated 27.04.2016. The EAC has deliberated on the certified compliance report and found it to be satisfactory.

6. The EAC, in its 23rd meeting held during 3-5th May, 2017, has found that the final EIA/EMP report submitted by the PP is adequate. The EAC, in its 24th meeting held during 14-16th June, 2017 has recommended for correction in the minutes of the 23rd EAC meeting. The EAC after detailed deliberations, on the basis of the information and presentation made by the PP, has recommended the project for environmental clearance with certain conditions.

7. Based on the proposal and information submitted by the project proponent, and the recommendations of the EAC (Industry-2), the Ministry of Environment, Forest and Climate Change hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14th September 2006, subject to the compliance of the specific and general conditions as under:-

A. Specific Conditions:

- (i) 10 m wide green belt with trees shall be developed around the periphery of the existing and proposed unit. 33 % of the area shall be developed as green cover area with trees.
- (ii) Enterprises Social Commitment shall be implemented with atleast 5 % cost of the expansion project, for five years, covering RO drinking water facility (with all the modern facilities) in the identified villages and computer/smart class facilities for schools.
- (iii) PP shall plant 1000 trees/year (fruit bearing trees/native trees) for five years and maintain them.
- (iv) The proposed project shall not lead to any additional pollution load.
- (v) Continuous online (24 x7) monitoring to be installed for flow measurement and measurement of pollutants within the treatment unit. Data to be uploaded on company's website and provided to the respective RO of MEF&CC, CPCB and SPCB.

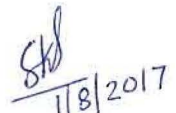
B. General Conditions:

- i. The project authorities must strictly adhere to the stipulations made by the Andhra Pradesh 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 stations 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 use the same water for the process activities of the project to conserve fresh water.
- 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, 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. 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.
- xiii. 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.
- 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&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.
- 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&CC 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://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.
- 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. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
9. The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.
10. 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 Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.


(S. K. Srivastava)
Scientist E

Copy to:-

1. The Secretary, Department of Environment, Forests, Science and Technology, Government of Andhra Pradesh, Secretariat, Hyderabad.
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-34
3. The Chairman, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar (Delhi)-32.
4. The Chairman, Andhra Pradesh Pollution Control Board, Paryavaran Bhavan, A-III, Industrial Estate, Sanath Nagar, Hyderabad.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, Jor Bhag, New Delhi- 3.
6. Guard File/Monitoring File/Website/Record File.


(S. K. Srivastava)
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