F.No.-J-11011/316/2017-IA-II(I)

Government of India

Ministry of Environment, Forest and Climate Change (IA Division)

Indira Paryavaran Bhawan Jor Bagh Road, New Delhi - 3 Dated: 14th November, 2017

To,

M/s Saiteja Drugs and Intermediates Pvt Ltd Sy. No. 543/A, 544/A, Seetavani Gudem Bhoodan Pochampally (M) District Yadadri - 508 284 (Telangana)

Sub: Manufacturing Active Pharmaceutical Ingredients (APIs) from API intermediates by M/s Saiteja Drugs and Intermediates Pvt Ltd at Sy. No. 543/A, 544/A, Seetavani Gudem (V), Bhoodan Pochampally (M), District Yadadri (Telangana) - Terms of Reference - reg.

Sir,

This refers to your proposal no. IA/TG/IND2/65449/2017 dated 15th June, 2017 on the subject matter, along with the project documents including Form-1, Pre-feasibility Report and the draft 'Terms of Reference' as per the EIA Notification, 2006.

- 2. It is noted that the proposal is for manufacturing Active Pharmaceutical Ingredients (APIs) by M/s Saiteja Drugs and Intermediates Pvt Ltd in an area of 2.4897 ha at Sy. No. 543/A, 544/A, Seetavani Gudem (V), Bhoodan Pochampally (M), District Yadadri (Telangana).
- 3. The project/activity is covered under category A of item 5(f) 'Synthetic Organic Chemicals' of the Schedule to the EIA Notification, 2006 and requires appraisal at Central Level by the Sectoral Expert Appraisal Committee (EAC) in the Ministry.
- **4.** The details of the products are as under:-
 - (a). Existing (as per CFO)

S.No.	Product	Quantity (TPA)
1.	1-Acetyl-4-(4-Hydroxy Phenyl) Piperzine	18
2.	5-Cyano Phthalide	18
3.	Cis-Bromo Benzoate	18
4.	Cis-Tosylate	18
Any one product at a time		18

(b). Proposed (as per EC dated 22nd August, 2007)

S. No.	Product	Quantity (TPA)	Therapeutic Category
1.	Sidenafil Citrate	36	Anti-erectile dysfunction agent
2.	Omeprazole	36	Anti-ulcerative
3.	Lansoprazole	36	Anti-ulcerative
4.	Pantoprazole	36	Anti-ulcerative
5.	Glimepiride	36	Anti-diabetic
6.	Clopidogrel Hydrogen Bisulfate	36	Anti-thrombotic
Any three products at a time		108	

- **5.** Existing land area is 2.4897 ha and no additional land will be required for the proposed expansion. Greenbelt will be developed in an area of 33.13 % i.e., 0.8259 ha out of 2.4897 ha of area of the project.
- 6. The estimated project cost is Rs. 18.3 crores, including existing investment of Rs.14.8 crores. Total capital cost earmarked towards pollution control measures is Rs. 3.56 Crores (including the existing Rs. 0.96 Crores), and the recurring cost (operation and maintenance) will be about Rs 2.71 crores per annum. Total employment will be 25 persons as direct & 40 persons indirect after expansion.
- 7. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc. within 10 km distance. River Musi is flowing at a distance of 6 km in NW direction and Chinna Musi River is flowing at a distance of 2.3 km in SE direction.
- 8. Draft Terms of Reference (ToR) were discussed and finalised during 29th Expert Appraisal Committee (Industry-2) meeting held in the Ministry during 12-13 October, 2017. The Committee has recommended the standard ToR applicable for such projects (refer Ministry's Website) for preparation of EIA/ EMP report, along with the additional Terms and conditions as under:-
 - (i) ESR plan for 5 years @2.5% of the project cost in consultation with nearby villagers to be submitted.
- (ii) Layout plan earmarking space for development of green belt of 5 m width along the plant periphery, and also ensuring 33% of the project area to be developed as green area with native species plantation.
- (iii) Compliance report for the existing environmental clearance, if any, duly certified by the concerned Regional Office of the Ministry to be submitted.
- **9.** Based on the recommendations of the EAC, the Ministry of Environment, Forest and Climate Change, hereby accords terms of reference for preparation of EIA/ EMP reports for the above said project, subject to the compliance of the standard ToRs applicable for such project/ activities and the additional terms and conditions as mentioned above.
- **10.** You are required to submit the final EIA/EMP report prepared by the consultants accredited with the Quality Council of India/National Accreditation Board of Education and Training (QCI/NABET), to the Ministry for grant of environmental clearance, within 3 years as per this Ministry's OM No. J-11013/41/2006-IA.II (I) dated 8th October, 2014.

(S. K. Srivastava)
Scientist E

Copy to:

- 1. The APCCF(C), MoEF&CC, Regional Office (SEZ), Ist and IInd Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, **Chennai** 34 (AP)
- The Member Secretary, Telangana Pollution Control Board, A-3, Paryavaran Bhavan, Sanath Nagar Rd, Sanath Nagar Industrial Estate, Sanath Nagar, Hyderabad - 18 (Telangana)
- 3. Guard File/ Monitoring File/ Website/ Record File