F. No. J-11011/393/2007-IA II (I) Government of India Ministry of Environment and Forests (I.A. Division)

Chairman's Office Inward No 129 Date 2097 Paryavaran Bhawan CGO Complex, Lodhi Road New Delhi – 110 003 E-mail: hanumant.singh@nic.in

Telephone : 011: 2436 7076Dated 16th August 2007

To.

M/s Granules India Ltd. (Paracetamol Div.)
Survey No. 533, 535 and 536 Industrial Development Area,
Bonthapally(V), Jinnaram(M),
Medak, A.P.

mail@granulesindia.com / nageshgvr@granulesindia.com Ph: 08458274433

Sub: Expansion of Bulk drug unit (Paracetamol 18 TPM to 1000 TPM) at Industrial Development Area, Bonthapally(V), Jinnaram(M),, Medak, A. P. by M/s Granules India Ltd. – Environmental Clearance reg.

Sir,

This has reference to your letter no. nil dated 24th April, 2007, along with Application in Form-I, and EMP, seeking environmental clearance for the above project under the Environment Impact Assessment Notification, 2006.

- 2.0 The Ministry of Environment and Forests has examined your application. It is noted that the proposal is for environmental clearance for expansion of Bulk drug manufacturing (Paracetamol 18 TPM to 1000 TPM) at Industrial Development Area, Bonthapally, Jinnaram, Medak, A. P. by M/s Granules India Ltd. Total land acquired is 3 Ha.
- 3.0 Total cost of the project is Rs. 25.00 Crores. Rs. 1.32 Crores towards capital cost and Rs. 19.58 Lakhs towards recurring cost/annum are earmarked for environmental pollution control measures respectively.
- Bag filters and Cyclone separators will be provided to control air emissions. No new air emissions will be added except 500 KVA DG set. Total ground water requirement will be reduced from 110 m³/day to 108 m³/day and will be purchased through tankers. Generation of wastewater will decrease from 58 m³/day to 51.5 m³/day due to reuse of water in the process. The effluent generated will be treated in ETP and then sent to CETP, JETL at Jeedimetla for further treatment and disposal.

Appeb Missent

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5.0 The Ministry of Environment and Forests hereby accords environmental clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 subject to compliance of the following specific and general conditions:

A SPECIFIC CONDITIONS:

- The project authorities shall comply with the stipulations made by ministry in its environmental clearance letter issued earlier vide F. No. J-11011/29/2004-IA.II(I).
- The company shall install high efficiency bag filters and multi-cyclone separators to improve the ambient air quality in and around the plant. The company shall submit a complete action plan to the Ministry's Regional Office/CPCB/SPCB within three months from date of issue of this letter under intimation to this office.
- iii) The company shall obtain permission from CGWA/SGWA for consumption of ground water. All the conditions/recommendation of Ground water Department shall be implemented. The company shall not exceed the water requirement and waste water generation as 108 m³/day and 51.5 m³/day respectively.
- iv) As proposed, green belt shall be provided in 1.66 ha to mitigate the effects of fugitive emissions all around the plant as per the Central Pollution Control Board guidelines.
- v) The effluent shall be segregated into low and high TDS streams. High TDS process effluent shall be neutralized and passed through MEE. Part of the condensate (75%) shall be reused in the process whereas extra condensate (25%) shall be sent to CETP, JETL at Jeedimetla for further treatment and disposal. MEE salts shall be sent to TSDF/HWMP for further treatment and storage.
 - vi) The company shall eliminate the 1st and 2nd stages of hydrolysis and reduction stage to reduce generation of high TDS wastewater and Iron sludge.
- vii) The company shall increase recovery of acetic acid by avoiding pH adjustment with caustic soda flakes at acetylation stage and reduce organic load in the wastewater by recovery of 31% acetic acid from mother liquors.
 - viii) The Company shall ensure that no increase in pollution load due to expansion.
 - ix) The Company shall maintain valid membership of CETP, JETL at Jeedimetla and TSDF at Dundigul.

B. GENERAL CONDITIONS:

(i) The project authorities shall strictly adhere to the stipulations of the SPCB/state government or any statutory body.

- No further expansion or modifications in the plant shall be carried out without (ii)prior approval of the Ministry of Environment and Forests. 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
- At no time, the emissions shall exceed the prescribed limits. In the event of (iii) failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired
- The gaseous emissions (SO2, NOx) and particulate matter along with RSPM (iv) levels from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- The locations of ambient air quality monitoring stations shall be reviewed in (v) consultation with the State Pollution Control Board (SPCB) and additional stations shall be installed, if required, in the downwind direction as well as where maximum ground level concentrations are anticipated.
- (vi) Dedicated scrubbers and stacks of appropriate height as per the Central Pollution Control Board guidelines shall be provided to control the emissions from various vents. The scrubbed water shall be sent to ETP for further treatment.
- All the storage tanks shall be under negative pressure to avoid any leakages. Breather valves, N2 blanketing and secondary condensers with brine chilling system shall be provided for all the storage tanks to minimize vapour losses. All liquid raw material shall be stored in storage Tanks and Drums.
- The company shall undertake following Waste Minimization measures. (viii)
 - Metering and control of quantities of active ingredients to minimize waste.
 - Reuse of by-products from the process as raw materials or as raw material
 - Use of automated filling to minimize spillage.
 - Use of "Close Feed" system into batch reactors.
 - Venting equipment through vapour recovery system.
 - Use of high pressure hoses for equipment cleaning to reduce wastewater generation.

- (ix) Fugitive emissions in the work zone environment, product, and raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by the State Pollution Control Boards/Central Pollution Control Board.
- (x) The project authorities shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October, 1994 and January, 2000 and Hazardous Waste (Management and Handling) Rules, 1989, as amended from time to time. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
- (xi) 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).
- (xii) The company shall develop rain water harvesting structures to harvest the run off water for recharge of ground water.
- (xiii) Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act.
- (xiv) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment. The eco-development plan should be submitted to the SPCB within three months of receipt of this letter for approval.
- (xv) The project proponent shall also comply with all the environmental protection measures and safeguards proposed in the EIA/EMP report.
- (xvi) A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- (xvii) The project authorities shall earmark adequate funds to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.
- (xviii) The implementation of the project vis-à-vis environmental action plans shall be monitored by the concerned Regional Office of the Ministry/SPCB / CPCB. A

six monthly compliance status report shall be submitted to monitoring agencies and shall be posted on the website of the Company.

- The project proponent shall inform the public that the project has been accorded (xix) 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://envfor.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.
- The project authorities shall inform the Regional Office as well as the Ministry, (XX)the date of financial closure and final approval of the project by the concerned
- The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.

The above conditions will be enforced, inter-alia under the provisions of the Water(Prevention & Control of Pollution) Act,1974, Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Wastes (Management and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991

(H.S. Malviya)

Copy to:

1. The Secretary, Forests & Environment Department, Government of Gujarat, Sachivalaya, 8th Floor, Gandhi Nagar-382 010, Gujarat.

2. The Chief Conservator of Forests (Western Zone), Ministry of Environment & Forests, Regional Office, E-5, Arera Colony, Link Road -3, Bhopal -462 016.

3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.

4. Phe Chairman, Gujarat State Pollution Control Board, Paryavaran Bhawan, Sector

5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO 6. Guard File.

Monitoring File.

8. Record File.

(H.S. Malviya) Joint Director