F. No. J-11011/15/2007- IA II (I)
Government of India
Ministry of Environment and Forests
(I.A. Division)

Paryavaran Bhawan
CGO Complex, Lodhi Road
New Delhi – 110 003

E-mail : pb.rastogi@nic.in
Telefax : 011: 2436 7668
Dated 17th May, 2007

To,

Shri V.S. Ambegaoker
Vice President (Works)
M/s Lupin Ltd.
124, GIDC Estate
Ankleshwar-393002
Gujarat

E-mail : udayanambegaokar@lupinpharma.com / harishnarula@lupinpharma.com
Fax No. : 02646-251868, 022-66402056

Sub: Expansion of bulk drug unit at Plot No. 9, 123, 123/1, 124 and 125, GIDC, Industrial Estate, Ankleshwar, Bharuch, Gujarat by M/s Lupin Ltd.

Sir,

This has reference to your letter no. ENV/EC/1512 dated 15th December, 2006 on the above subject alongwith EIA/EMP report, questionnaire, pre-feasibility report and Form I and subsequent communications dated 22nd February, 2007, 27th February, 2007, 5th March, 2007 and 9th March, 2007 seeking environmental clearance for the above project under the Environmental Impact Assessment Notification, 2006.

2.0 The Ministry of Environment and Forests has examined your application alongwith EIA/EMP report. It is noted that the proposal is for expansion of bulk drug unit at Plot No. 9, 123, 123/1, 124 and 125, GIDC, Notified Industrial Estate, Ankleshwar, Bharuch, Gujarat as per details given below:

S.N.	Name of products	Production Capacity (MT/Annum)		
		Existing	Addition	Total
Bulk Drug :				
1	Ethambutol Hydrochloride	720	+1,080	1,800
Bulk Drug Intermediates:				
2	7-Amino Deacetoxy Cefalosphranic Acid (7-ADCA)	1,140	+660	1,800
3	7-Amino –3-Chloro Cefalosphranic Acid (7-ACCA)	144	+96	240
4	D&L Mandelic Acid	180	+420	600
5	7-AVCA	-	+120	120
6	7-APCA	-	+120	120

7	7-Amino Ester	-	+120	120
8	Cefpodoxime Acid	-	+120	120
9	S-(+)-2-Aminobutyramide Hydrochloride	-	+120	120
10	S-(+)-2-Amino Bytyric Acid HCL	-	+180	180
11	2S-3-(dimethylamino)-1-(3-methoxypheny)-2-methylpropan-1-one	-	+24	24
				By-products (Chemicals)
12	Calcium Sulphate	9,348	+14.230	23,578
13	Sodium Chloride	396	+594	990
14	Meso	40	+61	101
15	Aminobutanol	600	+899	1,499
16	Dilute Sulfuric acid	13,110	+7,590	20,700
17	Phenyl acetic acid solution	2,029	+1,274	3,303
18	Dilute acetic acid	8,409	+4,868	13,277

Expansion will be within the existing site measuring 1,51,314 m^2. No national park and wildlife sanctuary is located within 10 km. of the project.

3.0 Caustic scrubber and water scrubber will be provided to control emissions. Total water requirement from GIDC water supply will be 2,874 m^3/d. Low COD effluent will be treated in ETP and high COD effluent, liquid organic waste as well as solid waste will be incinerated. Treated wastewater will be disposed off in GIDC drain for further treatment in CETP. Treated effluent will be finally discharged to deep sea through FETP of M/s BEAIL pipeline. Reverse Osmosis plant will be installed to reduce water consumption by recycling and reusing treated wastewater. Solid waste will be generated in the form of ETP sludge, incinerator ash, spent resin, spent carbon, process waste and used oil. All hazardous waste will be incinerated within the premises and solid waste will be sent to TSDF facility of M/s BEAIL.

4.0 No public hearing is required due to location of the project in notified GIDC Industrial area. Total cost of the project is Rs. 46.90 Crores.

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

A SPECIFIC CONDITIONS :

i) The gaseous emissions (SO_2, HCl & NO_x) and particulate matter 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. Inter-locking facility and on-line monitoring system shall also be provided and data shall be submitted to the Ministry's Regional Office at Bhopal / GPCB / CPCB regularly.

ii) Fugitive emissions in the work zone environment, product, raw material storage area shall be regularly monitored. The emissions shall conform to the limits imposed by GSPCB. Caustic scrubber and water scrubber shall be provided to control emissions.

iii) Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. Action shall be taken to reduce the emissions as far as possible. Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum. All venting equipment shall have vapour recovery system.

iv) The company shall undertake following Waste Minimization measures :-

- 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 substitutes in other processes.
- 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 clearing to reduce wastewater generation.

v) Total water requirement from GIDC water supply and effluent generation shall not exceed 2,874 m^3/day and 1,601 m^3/day respectively. Low COD effluent shall be treated in ETP having primary, secondary and tertiary treatment facilities. High COD effluent, liquid organic waste and residual solids shall be incinerated in the incinerator. Treated wastewater shall be disposed off in GIDC drain for further treatment in CETP. Treated effluent shall be finally discharged to deep sea through FETP of M/s BEAIL pipeline. Reverse Osmosis plant shall be installed to reduce water consumption by recycling and reusing treated wastewater. The domestic effluent shall be treated in septic tank and disposed off in a soak pit.

vi) All the solid/hazardous waste including RO rejects, activated carbon, spent carbon, spent catalyst, expired drugs, liquid waste, waste lubricating oil, spent solvent and terry waste etc. shall be incinerated in the existing incinerator. ETP sludge and incinerated ash shall be stored in HDPE bags in secured landfill and sent to the TSDF developed by M/s Bharuch Eco-Aqua Infrastructure Ltd. (BEAIL).

vii) The company shall develop rainwater harvesting structures to harvest the run off water for recharge of ground water.

viii) Green belt shall be provided in 50,000 m^2 (33 %) to mitigate the effects of fugitive emissions all around the plant. Development of green belt shall be as per the Central Pollution Control Board guidelines.

ix) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

B. GENERAL CONDITIONS :

i. The project authorities shall strictly adhere to the stipulations made by the Gujarat State Pollution Control Board.

ii. No further expansion or modifications in the plant shall be carried out without 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 required, if any.

iii. Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the GSPCB.

iv. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October, 1994 and January, 2000. Authorization from the GSPCB shall be obtained for collection, treatment, storage and disposal of hazardous wastes.

v. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the Gujarat State Pollution Control Board must be obtained for collection / treatment / storage / disposal of hazardous wastes.

vi. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) 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).

vii. The project proponent shall also comply with all the environmental protection measures and safeguards recommended in the EIA/EMP report.

viii. A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.

ix. As mentioned in the EIA/EMP, Rs. 2.50 Crores earmarked towards environmental pollution measures shall be judiciously used to implement the conditions stipulated by the Ministry of Environment and Forests as well as the State Government. An implementation schedule for implementing all the conditions stipulated herein shall be submitted to the Ministry, its Regional Office at Bhopal / GPCB / CPCB. The funds so provided shall not be diverted for any other purpose.

x. The implementation of the project vis-à-vis environmental action plans shall be monitored by the Ministry's Regional Office at Bhopal / GPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies.

xi. 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 GPCB/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 Ministry's Regional Office at Bhopal.

xii. 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.

6.0 The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

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

8.0 The above conditions will be enforced, inter-alia under the provisions of the Water (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 along with their amendments and rules.

17/5/07

(Dr. P.B. RASTOGI)
Additional Director

Copy to : -

1. The Secretary, Department of environment and forests, Govt. of Gujarat, Gandhi Nagar, Gujarat.
2. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office, Link Road No.3, E - 5, Arera Colony, Bhopal - 462 016. M.P.
3. The Chairman, Central Pollution Control Board Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi – 110 032.
4. The Chairman, Gujarat Pollution Control Board, Paryavaran Bhawan, Sector 10-A, Gandhi Nagar – 382 010, Gujarat.
5. Joint Secretary (CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, New Delhi.
7. Guard File.
8. Monitoring File.
9. Record File.

17/5/07

(Dr. P.B. RASTOGI)
Additional Director

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Paryavaran Bhawan
CGO Complex, Lodhi Road
New Delhi – 110 003

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Dated 27th July, 2007

To,

Vice President (Works)
M/s Lupin Ltd.
124, GIDC Estate
Ankleshwar-393002
Gujarat

Corrigendum

Attention is invited to the environmental clearance issued vide letter of even no. dated 17th May, 2007 to Expansion of bulk drug unit at Plot No. 9, 123, 123/1, 124 and 125, GIDC, Industrial Estate, Ankleshwar, Bharuch, Gujarat by M/s Lupin Ltd. Following corrections may be carried out in the letter :

1. In para 2, in the table after S.N. 18, the following may be added :

S. N.	NAME	Production Capacity (MTPA)		
		Existing	Addition	Total
	By-products (Chemicals):			
19	Ammonium chloride solution	13,116	+7,660	20,776
20	Recovered Ammonia solution	1,441	+3,663	5,104
21	Ammonium Bromide	587	+340	927
22	Sodium acetate	927	+617	1,544
23	Potassium bromide	185	+814	999
24	Recovered isobutyl chloride	276	+183	459
25	Ethyl acetate	442	+295	737
26	Para Toluene Sulphonic acid salt solution	852	+568	1,420
27	Sodium bromide solution	770	+651	1,421
28	TPPO (Tri Phenyl Phosphate)	301	+968	1,269
29	Potasium Chloride	123	+286	409
30	Boric acid	-	+102	102
31	MBT	-	+99	99
32	Ammonium Tartarate	-	+378	378

33	Dilute HCl	-	+362	362
34	Recovered IPA	-	+612	612
35	Recovered n-Propanol	-	+182	182
36	Recovered THF	-	+109	109

2. In Specific Condition item no. (V), the sixth sentence "Reverse Osmosis Plant shall be installed to reduce water consumption by recycling and reusing treated wastewater" stands deleted.

3. The Specific Condition no. (VI) :

   For : "All the solid/hazardous waste including RO rejects, activated carbon, spent carbon, spent catalyst, expired drugs, liquid waste, waste lubricating oil, spent solvent and terry waste etc. shall be incinerated in the existing incinerator. ETP sludge and incinerated ash shall be stored in HDPE bags in secured landfill and sent to the TSDF developed by M/s.Bharuch Eco-Aqua Infrastructure Ltd. (BEAIL)".

   Read : "All the solid/hazardous waste including RO rejects, activated carbon, spent carbon, spent catalyst, expired drugs, liquid waste, waste lubricating oil and terry waste etc. shall be incinerated within the premises or common incinerator. ETP sludge and incinerated ash shall be stored in HDPE bags in secured landfill and sent to the TSDF developed by M/s Bharuch Eco-Enviro Infrastructure Ltd. (BEIL). Spent solvent shall be sold to authorized reprocessors".

4. All other conditions remain unchanged.

This issues with the approval of the Competent Authority.

(Dr. G.V. Subrahmanyam)
Director

Copy to : -

1. The Secretary, Department of environment and forests, Govt. of Gujarat, Gandhi Nagar, Gujarat.
2. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office, Link Road No.3, E - 5, Arera Colony, Bhopal - 462 016. M.P.
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(Dr. G.V. Subrahmanyam)
Director