भारत सरकार
पर्यावरण एवं वन मंत्रालय
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT & FORESTS

BY SPEED POST

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File No- J-11011/861/2007-IA II- (I)

Date: 10th January 2007

To,

M/s Sidmak Laboratories (India) Pvt. Ltd.
Plot No. 20, Pharmacity
Seleakui Industrial Estate
Chakrata Road, Dehradun
Uttranchal

Subject: **Enhancement in Manufacturing Capacity of Formulation Plant at Plot No. 20, Pharmaccity Selaqui Industrial Estates, Chakrata Road, Dehradun, Uttrakhand by M/s Sidmak Lab. (P) Ltd.- Environment Clearance Regarding.**

Sir,

Kindly refer to your application No. Nil dated 24th June 2007 seeking environmental clearance under the Environmental Impact Assessment Notification, 2006.

2. The Ministry of Environment and Forests has examined the proposal. It is noted that the proposal is for expansion of Pharma Formulation Manufacturing Capacity at the existing site at Plot No. 20, Pharmacity, Selaqui Industrial Estate, Chakrata Road, Dehradun, Uttrakhand. The cost of the expansion will be Rs. 5.0 Crores, out of which Rs. 12.0 Lacs will be earmarked for environmental protection measures. The total area of the project is 0.651 ha, out of which 0.2 ha will be developed as green belt. There are 15 Reserve Forests within 10 km area of the site. The Project does not involve any R & R. No endangered species of flora and fauna has been reported. The list of the products to be manufactured at the site is as follows-

(i) Tablets	-	15 Lac/day to 30 Lac/day
(ii) Capsules	-	6.75 Lac/day to 13.5 Lac/day
(iii) Topical preparation	-	20,000 Tubes/day

3 The raw materials required will be 3000 Kg/day of Actives and excipients, 1300000 Kg/day of empty gelatin capsules and 300 Kg/day Sugar. Power requirement for the expansion project will increase from 750 KVA to 1000 KVA per day which will be sourced from Uttrakhand State Electricity Board (USEB). 22 Kg/hr of LPG as fuel will be used for two IBR type boilers. The maximum manpower requirement will be 190. Water requirement of 20 KLD will increase to 30 KLD which will be sourced

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from State Industrial Development Corporation of Uttrakhand Ltd. (SIDCUL) supply or exiting bore wells. The wastewater treatment will be carried out in ETP upto tertiary treatment, and the ETP sludge will be used as manure. There will be no discharge of wastewater outside the plant premises. The treated water will be used for Green belt development / plantation and washing etc, thereby maintaining 'Zero Discharge'. From the expansion, the solid waste generated will be 1600 Kg/month of PVC foil and 400 Kg/month of Aluminium foil which will be sold to authorized vendors.

4. The project activity is not listed under the EIA Notification, 2006, however is of Orange Category under the Doon Valley Notification, 1989 requiring environment clearance from the Central Government. Public Hearing for the project has been dispensed with as per Para 7(ii) of EIA Notification, 2006 since the project is an expansion/ modernization.

5. Based on the information submitted by you, the Ministry of Environment and Forests hereby accords environmental clearance to the above project under the provisions of EIA Notification dated 14th September 2006 and Doon Valley Notification, 1989 subject to compliance of the following conditions:

A. SPECIFIC CONDITIONS:

(i) Stack of appropriate height as per the CPCB guidelines shall be provided for the boiler and shall be designed with air pre-heater for achieving higher fuel efficiency and dispersion of pollutants. For control of process emission, wet scrubbers and air handling unit with HEPA filters shall be installed. The exhaust of all coating equipment shall be connected to the scrubbers. Scrubbed water, after neutralization, shall be sent to ETP for further treatment.

(ii) There shall be no odour nuisance from products & materials used.

(iii) Water requirement shall not exceed 30 KLD which will be sourced from State Industrial Development Corporation of Uttrakhand Ltd. (SIDCUL) supply or from the exiting bore wells.

(iv) An ETP up to tertiary treatment and of 20 KLD capacity shall bee installed for treatment of wastewater. The treated water shall be used for Green belt development / plantation and washing etc. and there shall be no discharge of wastewater outside the plant premises thereby maintaining Zero discharge.

(v) 1600 Kg/month of PVC foil and 400 Kg/month of Aluminium foil generated from the expansion shall be sold to authorized vendors. Packaging material like damaged cartons, paper waste, shipper & corrugated boxes etc. shall be crushed into small

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pieces and sold to UEP & PCB authorized scrap dealers. 10 - 15 Kg/day of ETP sludge shall be dried and utilized as manure for green belt development. Other wastes like drums, gunny bags etc. Shall be sold to authorized recyclers.

(vi) All the residue & wastes, off specification Drugs and Formulations, flue gas cleaning residue from the process etc. shall be either sent to TSDF for land filling or for incineration. Solid/hazardous waste shall be characterized and report submitted to the Regional Office of this Ministry at Lucknow, UEP & PCB and a decision regarding further disposal to the TSDF / incinerator shall be taken accordingly.

(vii) Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.

(viii) Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. Solvent vapours emitted during purification process from purification tanks as fugitive emissions shall be reduced as far as possible. All venting equipment shall have vapour recovery system and condensers used for solvent recovery shall be monitored periodically.

(ix) Regular monitoring of HC and VOC shall be carried out in solvent storage areas, at all vents, in work zone area and in the ambient air at probable locations in and around the plant.

(x) 0.2 ha shall be developed as green belt with suitable species of the plants as per the CPCB guidelines.

(xi) The project authorities shall earmark Rs. 12.0 Lacs as recurring expenditure 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.

(xii) Prior permission from the Chief Wildlife Warden and State Forest regarding impact of the proposed unit on the Reserve Forests around the units shall be obtained and all the recommendations suggested shall be implemented.

B. GENERAL CONDITIONS :

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

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(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) At no time, the emissions shall exceed the prescribed limits. In the event of 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 efficiency has been achieved.

(iv) The gaseous emissions (SO_2, NO_x, HCl, NH3, CO, VOC and HC) and Particulate matter along with RSPM 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.

(v) The locations of ambient air quality monitoring stations shall be reviewed in 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.

(vii) All the storage tanks will be under negative pressure to avoid any leakages. Breather valves, N_2 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. Closed handling systems for chemicals and solvents will be provided. Magnetic seals will be provided for pumps/agitators for reactors for reduction of fugitive emissions. Solvent traps shall be installed wherever necessary. Reactor generating solvent vapors will be connected to condensers with receivers.

(viii) All venting equipment shall have vapour recovery system. All the pumps and other equipment's where there is a likelihood of HC leakages shall be provided with Leak Detection and Repair (LDAR) system and LEL indicators and

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Hydrocarbon detectors. Provision for immediate isolation of such equipment, in case of a leakage will also be made. The company shall provide a well defined Leak Detection and Repair (LDAR) programme for quantification and control of fugitive emissions. The detectors sensitivity will be in ppm levels.

(ix) 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 cleaning to reduce wastewater generation.

(x) 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. Dust / powder from the manufacturing process shall be collected by dust extractor.

(xi) 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. All Transportation of Hazardous Chemicals shall be as per the MVA, 1989.

(xii) 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).

(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) 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.

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(xv) Usage of PPEs by all employees/ workers shall be ensured.

(xvi) The company shall strictly follow all the recommendations mentioned in the Charter on Corporate Responsibility for Environmental Protection (CREP).

(xvii) The Company shall harvest surface as well as rainwater from the rooftops of the buildings proposed in the expansion project and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water.

(xviii) The project proponent shall also comply with all the environmental protection measures and safeguards proposed in the EIA/EMP report. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented.

(xix) The company will undertake all relevant measures for improving the Socio-economic conditions of the surrounding area. CSR activities will be undertaken by involving local villages and administration

(xx) The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.

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

(xxii) 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.

(xxiii) 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.

(xxiv) 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://envfor.nic.in. This shall be advertised within seven

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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.

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

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

8. 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 Wastes (Management and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

(**Sanchita Jindal**)
Additional Director

Copy to:

1. Secretary, Department of Environment, Government of Uttarakhand, Dehradun, Uttarakhand.

2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi - 110032.

3. The Chairman, Uttranchal Environmental Protection and Pollution Control Board, E-115, Nehru Colony, Dehradun, Uttarakhand.

4. The Chief Conservator of Forests, Regional Office (Central Region), Kendriya Sadan, Sector H, 5th Floor, Aliganj, Lucknow - 226 024, U.P.

5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.

6. Guard file/Record file/Monitoring file.

(**Sanchita Jindal**)
Additional Director