Environment clearance

भारत सरकार
पर्यावरण एवं वन मंत्रालय
Government of India
Ministry of Environment & Forests
(IA Division)

Paryavaran Bhawan
CGO Complex, Lodhi Road
New Delhi – 110 003
E-mail: plahujarai@yahoo.com
Telefax: 011: 2436 3973

F. No. J-11011/1313/2007- IA II (I)

Dated: February 2, 2009

To,

M/s Nutra Specialities Private Limited
No. 5, Vivekananda Street
Spur Tank Road,
Chetpet, Chennai – 600 031

E mail: **marketing@nutraforlife.com**

Sub : Expansion of Bulk Drug Unit at District Nellore Vinjamum Mandal Andhra Pradesh by M/s Nutra Specialities Private Limited – environmental clearance reg.

Sir,

This has reference to your letter No. nil dated 4th November, 2008 along with copies of EIA/EMP and public hearing reports seeking environmental clearance under the provisions of Environmental Impact Assessment Notification, 2006 on the above mentioned subject.

2. The Ministry of Environment and Forests has examined your application. It is noted that M/s Nutra Specialities Pvt. Ltd. have proposed for expansion of bulk drugs manufacturing Unit from 60.72 TPA to 142.32 TPA in district Nellore in Andhra Pradesh. Out of 38 acres of the land area available, green belt will be developed over 25 acres of land. The major forests in the study area are Rajavulu Reserve forest which is at a distance of 0.5 km in SW direction to the plant site, Abbasahebupeta GudiPadu & Pedda Annularu RF at a distance of 8.5 km in NE Direction, Rajavulu Punugodu RF at a distance of 4.5 km in SE direction and Bayila Chiruvella RF at a distance of 7.5 km in SW direction from the plant site. No eco-sensitive areas like national parks/ wildlife sanctuaries etc are located within 15 km periphery of the plant. The total cost of the project is Rs. 12 Crores.

3. Details of products along with their production capacities are given below:

S.No	Existing Products	Capacity Kg/Month
1	Solanesol	2500
2	Ubequinone	2000
3	Tetrohydrocur cumin	80
4	Glucasomine	80
5	10-DAB-III	80

6	Thiocochicoside	80
7	Tacrolimus	80
8	Digoxin	80
9	Hyoscine Butyl Bromide	80
Total	**5060**	

Any three products manufactured on campaign basis.

Capacities of the Proposed products include the following:

S.No	Proposed Product	Capacity* (Kg/month)
1	Iron Sucrose	1000
2	Iron Sorbitol	1000
3	Olmesartan Medoxomil	500
4	Boswellic Acid	500
5	Capacitabine	100
6	Tioconozole	200
7	Ezitamibe	200
8	Sertraline HCl	500
9	Moxiflaxacin	500
10	Tetracaine Hydrochloride	500
11	Nebivilol HCl	200
12	Warfarine Sodium	500
13	Vitamin K2/4	100
14	Policosanol	500
15	Teprenone	500
Total		**6800**

Byproducts

S.No	Name of the Product	Name of By-Product	Kg/Month
1	Olmesartan medoxomil	NaBr	170
2	Tioconozole	NaBr	53.25
3	Teracaine Hydrochloride	NaBr	171.25
4	VitaminK2/4	Potassium Iodide	37.75
5	Teprenone	NaBr	435.75

4. It is noted that water requirement for the plant will be 173.8 m3/d and sourced from bore well. The total waste water generation from the plant will be 67.03 m3/d. The waste water (14.23 m3/d) from process and washings will be forced evaporated. The condensate will be treated in an aerobic treatment system and the treated waste water will be reused for on land irrigation. The condensate from the Multiple Effect Evaporator will be given biological treatment along with

washings. The concentrate will be sent to TSDF. The boiler blow downs (11.8m3/d) and cooling tower blow down (35m3/d) will be treated in effluent treatment plant and treated effluent will be used for green belt development within plant premises. The domestic waste water (6 m3/d) generated will be sent to septic tank followed by soak pit. The total power requirement of the plant after expansion will be 1500 KVA. About 16 TPD of coal will be used for 3 TPH boiler. The sources of air pollution from the plant will be coal fired boiler, 2TPH oil fired boiler and DG set of 500 KVA. Multi cyclone will be installed to control particulate emissions from the coal fired boiler and emissions shall be dispersed through chimney and height as per CPCB standards. Stack height of 23 m, 8.5 m and 5 m will be provided to control the gaseous emissions from the 3 TPH coal fired boiler, 2 TPH oil fired boiler and 500 KVA DG set respectively. The scrubbers will be installed to control HCl and HBr emissions. The scrubbed solution (33% of HCl) will be reused as raw material.

5. The project activity is listed at serial no. 5(f) of schedule of EIA Notification, 2006 and categorized under "A" Category. The Expert Appraisal Committee (Industry) considered the project in the meeting held on 25th -26th November, 2008. The Committee recommended the proposal for grant of environmental clearance. Public hearing of the project was held on 26.9.2008.

6. Based on the information submitted by the project authorities, the Ministry of Environment and Forests hereby accords environmental clearance to above project under the provisions of EIA Notification, dated 14th September 2006 subject to the compliance of the following Specific and General Conditions.

A. SPECIFIC CONDITIONS:

i. The company shall implement Good Laboratory Practices (GLP)

ii. The gaseous emissions (HBr , SOx, NOx, & HCl) particulate matter from various process units shall conform to the standards prescribed by the concerned authorities form 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.

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 SPCB.

iv. Process emissions is in the form of HCl, SO2 and HBr shall be scrubbed in the scrubber. The scrubber efficiency shall be 99%.

v. For control of particulate emissions, boilers shall be provided with cyclones separators and stack height as per Central Pollution Control Board guidelines.

vi. Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapours are emitted from purification tanks as fugitive emissions. Action shall be taken to reduce the emission as far as possible. All venting equipment shall have vapour recovery system.

vii. 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.

viii. 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 SPCB.

ix. The project authorities shall provide the chilled brine solution in secondary condenser for condensation of the VOCs and ensure that the solvent recovery shall not be less than 95%.

x. The company shall provide the monitoring arrangement with vents and regular monitoring shall be carried out and reports submitted to the SPCB, CPCB and Ministry's Regional Office at Bangalore.

xi. To prevent solvent loss, following measures shall be taken :

i. Reactor shall be connected to chilled brine condenser system
ii. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
iii. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
iv. Solvents shall be stored in a separate space specified with all safety measures.
v. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
vi. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

xii. The process emissions VOCs and particulate matter from various 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 unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.

xiii. Effluent generation shall not exceed 67.03 m3/d. The effluent shall be segregated into high COD and low COD streams. The high COD effluent shall be forced evaporated. The effluent with high COD shall be stripped for solvents before sending into the forced evaporator. The condensate from the evaporator and effluent from the utility blow downs shall be treated in ETP and treated effluent conforming to the prescribed standards shall be used for green belt development. The concentrate from MEE shall be filter press. The salt obtained from MEE shall be disposed into secured land fill (TSDF) after packaging in HDPE bags. The domestic effluent (6m3/d) shall be sent to septic tank followed by soak pit.

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

xv. Green belt shall be provided in an area of 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.

xvi. Permission shall be obtained to draw ground water from the State Ground Water Board/Central Ground Water Board as may be applicable to this case.

xvii. 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 Andhra Pradesh State Pollution Control Board.

ii. 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.

iii. 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.

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 SPCB shall be obtained for collection, treatment, storage, 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, Handling and Transboundary Movement) Rules, 2008. Authorization from the State Pollution Control Board must be obtained for collections/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. 75dBA (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 Environmental Impact Assessment Notification,1994 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. The project authorities shall earmark separate 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.

x. The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office at Bangalore/ SPCB/Central Pollution Control Board . 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 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 Ministry's Regional Office at Bangalore.

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.

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

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

9. Any appeal against this environmental clearance shall lie with the National Appellate Authority, if preferred, within a period of 30 days as prescribed under section 11 of the National Environment Appellate Authority Act, 1997.

10. 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, Handling and Transboundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

(Dr. P. L. Ahujarai)
Director

Copy to :-

1. The Secretary, State Deptt. of Environment, Government of Andhra Pradesh, Mantralaya, Hyderabad.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
3. The Chairman, Andhra Pradesh State Pollution Control Board, 2nd Floor, HUDA Complex, Maitrivaram , S.R.Nagar, Hyderabad- 500 038.
4. The Chief Conservator of Forests (Central), Regional Office (SZ), Kendriya Sadan, IVth Floor, E&F Wing, 17th Main Road, Koramangala, Bangalore-560034.
5. JS(CCI-I), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.- 110003.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi- 110003.
7. Guard file./Record file/Monitoring file.

(Dr. P. L. Ahujarai)
Director