

F. No. J-11011/47/2009- 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 21st December, 2010

To, ✓
 Shri Sucheth Rao Davuluri, CEO
 M/s Neuland Laboratories Limited
 204, Meridian Plaza, 6-3-854/1 Ameerpet
 Hyderabad - 500016, A.P.

E-mail: skmittal@neulandlabs.com; neuland@neulandlabs.com ; Fax No.: 91-40-23412957

CORRIGENDUM

Subject : Bulk Drug Unit at Village Isnapur, Tehsil Patancheru, District Medak in Andhra Pradesh by M/s Neuland Laboratories Limited - Change in product mix reg.

Ref. : 1. Ministry's letter no. J-11011/27/2004-IA 11(1) dated July 15, 2005.
 2. Your letter no. nil dated 18th May, 2010.

Sir,

Attention is invited to this Ministry's letter of even no. dated July 15, 2005 and your letter dated 18th May, 2010 on the above subject informing about the change in product mix without increase in total capacity of the drugs. The matter was discussed in the 12th & 15th Expert Appraisal Committee (Industry-2) meeting held during 15th-16th July, 2010 & 22nd - 23rd October, 2010. Following amendment may be incorporated in our letter dated July 15, 2005:

Para 2 :
For Group A :

| S. N. | Product Name | Consented Capacity (TPM) | | | Proposed Capacity (TPM) (Group-A) | | | | | |
|--------------|------------------------|-----------------------------|--------------------------|---|-----------------------------------|----------------------------|--|-----------|--------------|--------------|
| | | Capacity (Finished product) | Capacity (Inter-mediate) | Capacity (finished product & Intermediates) | Capacity (Finished product) | Capacity (Inter-mediate s) | Capacity (finished product & Intermediate s) | | | |
| 1 | Ciprofloxacin HCl | 3 | 16.48 | 19.48 | 35 | Nil | 35 | | | |
| 2 | Ranitidine HCl | 5 | 20.01 | 25.01 | 11 | 34.54 | 45.54 | | | |
| 3 | Norfloxacin | 1 | 4.81 | 5.81 | Dropped | | | | | |
| 4 | Pefloxacin | 1 | 5.65 | 6.65 | | | | | | |
| 5 | Sotalol HCl | 0.15 | 0.44 | 0.59 | | | | | | |
| 6 | Enalapril Maleate | 0.125 | 0.955 | 1.08 | | | | | | |
| 7 | Ofloxacin | 1 | 6.32 | 7.32 | | | | | | |
| 8 | Ketoralac Tromethamine | 0.5 | 18.84 | 19.34 | | | | | | |
| TOTAL | | 11.775 | 73.51 | 85.28 | | | | 46 | 34.54 | 80.54 |

For Group B :

| S. N. | Product Name | Consented | | | Product Name | Proposed (Group-B) | | | | | |
|-------|------------------------|---------------------------------|------------------------------|---|------------------------|---------------------------------|------------------------------|---|-----|-------|------|
| | | Capacity TPM (Finished product) | Capacity TPM (Inter-mediate) | Capacity TPM (finished product and Intermediates) | | Capacity TPM (Finished product) | Capacity TPM (Inter-mediate) | Capacity TPM (finished product and Intermediates) | | | |
| 1 | Ciprofloxacin HCl | 3 | 16.48 | 19.48 | Ciprofloxacin HCl | 35 | Nil | 35 | | | |
| 2 | Ranitidine HCl | 5 | 20.01 | 25.01 | Ranitidine HCl | 8 | 25.12 | 33.12 | | | |
| 3 | Norfloxacin | 1 | 4.81 | 5.81 | Norfloxacin | Dropped | | | | | |
| 4 | Pefloxacin | 1 | 5.65 | 6.65 | Pefloxacin | | | | | | |
| 5 | Sotalol HCl | 0.15 | 0.44 | 0.59 | Sotalol HCl | | | | | | |
| 6 | Enalapril Maleate | 0.125 | 0.955 | 1.08 | Enalapril Maleate | | | | | | |
| 7 | Ofloxacin | 1 | 6.32 | 7.32 | Ofloxacin | | | | | | |
| 8 | Ketoralac Tromethamine | 0.5 | 18.84 | 19.34 | Ketoralac Tromethamine | | | | | | |
| | | | | | Nonane | | | | 0.2 | 5.016 | 5.21 |
| | | | | | Entacapone | | | | 0.2 | 0.26 | 0.46 |
| | | | | | Aripiprazole | 0.1 | 0.132 | 0.23 | | | |
| | | | | | Montelukast Sodium | 0.1 | 0.324 | 0.42 | | | |
| | Total: | 11.775 | 73.51 | 85.28 | Total: | 43.6 | 30.852 | 74.44 | | | |

2.0 All the other specific and general conditions will remain same as stipulated in the Ministry's letter no. J-11011/27/2004-IA 11(1) dated July 15, 2005 and shall be satisfactorily complied. No change in the product mix or expansion/modification shall be carried out without prior approval from the Ministry.

3.0 This letter may be kept with the original environmental clearance letter.

4.0 This letter has been issued with prior approval from the Competent Authority in the Ministry.

P. B. Rastogi
(Dr. P.B. Rastogi)
Director

Copy to :

1. Principal Secretary, Department of Environment, Forest, Science & Technology, Government of Andhra Pradesh,
2. The Chairman, Andhra Pradesh Pollution Control Board, Paryavaran Bhawan, A-III, Industrial Estate, Sanath Nagar, Hyderabad - A.P.
3. The Chief Conservator of Forests, Regional Office (Southern Zone, Bangalore) Kendriya Sadan, 4th Floor, E&F Wing, II Block Koramangala, Bangalore-560034.
4. Adviser, IA II, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, New Delhi.
5. Guard File/Monitoring File/Record File.

P. B. Rastogi
21/12/10
(Dr. P.B. Rastogi)
Director



State Level Environment Impact Assessment Authority (SEIAA)
Telangana State
Government of India
Ministry of Environment Forests & Climate Change
Block No.305, Maitri Vihar, Ameerpet, Hyderabad – 500 083

REGD.POST WITH ACK.DUE

Order No. SEIAA/TS/OL/SRD-454/2023-

Dt:24.07.2023.

Sub: SEIAA, TS – M/s. Neuland Laboratories Limited (Unit -2), Plot No.92-94, 257-259, Phase – II, IDA, Pashamailaram, Sangareddy District – Amendment to Environmental Clearance – Issued - Reg.

Ref:

1. EC issued vide order dt.20.05.1995 by APPCB (Combined State).
2. EC issued vide order dt.15.07.2005 by MoEF, GoI, New Delhi.
3. EC (Corrigendum) issued vide order dt.12.12.2010 by MoEF, GoI, New Delhi.
4. Your EC Application submitted online on 15.05.2023 MODI-EC (proposal No. **SIA/TG/IND3/299377/2023**) accepted on 26.05.2023.

- I. Earlier, vide reference 1st cited the industry has obtained EC from APPCB (Combined State) for manufacturing Bulk Drugs. Subsequently, vide reference 2nd cited the industry obtained EC (Ex-post facto clearance) for new product, obtained corrigendum to EC vide reference 3rd cited.
- II. Now, the proponent vide reference 4th cited the proponent has applied for Amendment of EC and requested to include DG sets in addition to the existing DG sets.

They requested to include the following wastes in Amendment to EC:

| S. No | Description | Quantity | Mode of Disposal |
|-------|---------------------------------------|-----------|--|
| 1 | Used PPE | 2 TPM | Shall be disposed to Cement Units for Co-processing / AFRF facilities for pre-processing (or) M/s. TSDF, Dundigal for preprocessing. |
| 2 | Insulation waste | 2 TPM | |
| 3 | Thermacoal waste | 1 TPM | |
| 4 | Stripper Distillate Quantity | 2.5 TPD | |
| 5 | Contaminated cotton waste | 0.2 TPM | |
| 6 | Molecular sieves | 0.2 TPM | |
| 7 | Off specification / Rejected products | 5 Kgs/day | |
| 8 | Used cooling tower frills | 0.1 TPM | |
| 9 | Used filter cloths | 0.2 TPM | |
| 10 | HDPE/PPFRP waste | 1.0 TPM | |
| 11 | Used Glass bottles | 0.2 TPM | After detoxification, it shall be disposed to outside agencies |
| 12 | Paper waste | 1.0 TPM | Disposed to recyclers / re processors |

Inclusion of DG Sets:

| S.No | As Per EC | Amendment |
|------|--|--|
| 1 | Attached to DG sets of capacity-1 x 380 KVA, 2 x 725 KVA & 1 x 250 KVA | Inclusion of Stand by DG sets of capacity-1 x 1250 KVA & 1 x 250 KVA |

The proponent informed that the DG Sets are old in Condition and requested for inclusion of Stand by DG Sets for Emergency or Break down in addition to the existing DG Sets.

Recovery of By Products:

- The Amendment is sought for sale of aqueous layer for Bempodoic acid in the form of Sodium iodide and Lithium Bromide.
- In Stage 1, HTDS effluent, 178.17 kgs/batch is selling to authorized vendor where recovers sodium iodide and lithium bromide.
- In Stage 2, HTDS effluent, 684.89 kgs/batch is selling to authorized vendor where recovers sodium iodide.

III. The request of the proponent was examined by the State Level Expert Appraisal Committee (SEAC) in its meetings held on **01.06.2023 & 14.06.2023**. Based on the information furnished presentation made by the proponent & the consultant M/s. Pragathi Labs & Consultants Pvt. Ltd., Hyderabad; the Committee considered the request of proponent and recommended to issue Amendment to the EC order. The State Level Environment Impact Assessment Authority (SEIAA), in its meeting held on **20.07.2023** examined the request of the proponent and the recommendations of SEAC, and decided to issue Amendment to the Environmental Clearance for inclusion of wastes and DG Sets only. The proponent shall obtain permission from TSPCB for recover of By-products as per the provisions of EIA Notification, 2006 & its amendments.

Hence, the following Amendments are made to the EC order issued vide references 3rd cited:

1) The details of waste generation & their disposal are as follows:

| S. No | Description | Quantity | Mode of Disposal |
|-------|---------------------------------------|-----------|--|
| 1 | Used PPE | 2 TPM | Shall be disposed to Cement Units for Co-processing / AFRF facilities for pre-processing (or) M/s. TSDF, Dundigal for preprocessing. |
| 2 | Insulation waste | 2 TPM | |
| 3 | Thermacoal waste | 1 TPM | |
| 4 | Stripper Distillate Quantity | 2.5 TPD | |
| 5 | Contaminated cotton waste | 0.2 TPM | |
| 6 | Molecular sieves | 0.2 TPM | |
| 7 | Off specification / Rejected products | 5 Kgs/day | |
| 8 | Used cooling tower frills | 0.1 TPM | |
| 9 | Used filter cloths | 0.2 TPM | |
| 10 | HDPE/PPFRP waste | 1.0 TPM | |
| 11 | Used Glass bottles | 0.2 TPM | After detoxification, it shall be disposed to Authorized recyclers / end users |
| 12 | Paper waste | 1.0 TPM | Disposed to authorized recyclers / re-processors |

2) Permitted DG Sets & their capacities:

- a) *Existing DG sets of capacity-1 x 380 kVA, 2 x 725 kVA & 1 x 250 kVA*
b) *New DG sets of capacity-1 x 1250 kVA & 1 x 250 kVA*

- IV. Officials from the TSPCB and Integrated Regional Office of MoEF&CC, GoI, Hyderabad who would be monitoring the compliance of the stipulated conditions and implementation of environmental safeguards should be given full co-operation, facilities and documents/data by the project proponents during their inspection. A complete set of all the documents shall be submitted to the CCF, Integrated Regional Office to MoEF&CC, GoI, Hyderabad.
- V. The proponent shall comply with Plastic Waste Management Rules, 2016 & also comply with MoEF & CC Notification No: G.S.R. 571 (E), dated: 12.08.2021 which mandated banning of usage of identified Single Use Plastic items with effect from 01.07.2022.
- VI. All other information mentioned and conditions stipulated in the EC order issued vide references 2nd & 3rd cited remain the same.

Sd/-
MEMBER SECRETARY
SEIAA, T.S.

Sd/-
MEMBER
SEIAA, T.S.

Sd/-
CHAIRMAN,
SEIAA, T.S.

To

**Sri Tapas Saha, Vice President – EHS,
M/s. Neuland Laboratories Limited, Unit-2,
Sy. No. 347, 473, 474 & 490/2,
Bonthapally (V), Jinnaram (M),
Medak District – 502 313
Ph. No. 7674889979
Email: tapassaha@neulandlabs.com**

Copy to:

1. Prof. Ch. Krishna Reddy, Chairman, SEAC, T.S. for kind information.
2. The Member Secretary, TSPCB for kind information.
3. The EE, RO: SR-I, TSPCB for information.
4. The Integrated Regional Officer, MoEF&CC, RO, Hyderabad for kind information.
5. The Secretary, MoEF&CC, GOI, New Delhi for kind information.

//T.C.F.B.O//


Joint Chief Environmental Engineer