DIRECTIONS

Whereas you are operating industry in the name & style of M/s. Gland Pharma (Formulation), Unit-II, Block-C, Phase-I, VSEZ, Duvvada, Visakhapatnam to manufacture of Liquid Vial Injections / Lyophilized Vial injections to the tune of 50,000 Nos/day.

Whereas the Board vide reference 1st cited, issued Consent for operation and Hazardous Waste Authorization to the industry on 23.05.2016, which is valid upto 31.07.2021 subject to the compliance of standards and conditions stipulated.

Whereas the EE, RO, Visakhapatnam vide reference 2nd cited, received a telephonic complaint on 19.12.2017 from the Villagers of Tanam, Parawada (M), Visakhapatnam regarding open burning of hazardous waste material and causing odour nuisance in the area.

Whereas the EE, RO, Visakhapatnam inspected the site on 19.12.2017 vide reference 3rd cited and observed the following:

1. A scrap vendor has stored about 200 Nos. of 200 LT HDPE empty drums on open ground and about 100 no. of black bags were stored openly. The bags were opened and observed that the bags are containing nose masks, head caps, gloves, empty vials and shredded QA documents.

2. On enquiry, the scrap vendor informed that the material belongs to Sri Srinu who is a scrap vendor from Hyderabad and storing the material in his godown. After verification of the bags randomly, labels of M/s. Gland Pharma Ltd., Unit – 2, VSEZ Duvvada were observed. The scrap vendor informed that the material belongs to M/s. Gland Pharma.

3. Further, the representative of M/s. Gland Pharma was contacted over cell phone and instructed to verify the waste whether the waste belongs to their industry or not.

4. Accordingly, the representative of M/s. Gland Pharma verified the material and informed that the material belongs to their industry and further informed they are regularly disposing the used PPE to M/s. Ramky Pharmacy, Parawada, Visakhapatnam.

Whereas legal hearing was conducted before the External Advisory Committee (Task Force) Meeting of A.P. Pollution Control Board on 28.12.2017 vide reference 4th cited. The representatives of the industry attended the legal hearing. The committee noted that telephonic complaint was received on 19.12.2017 by the EE, RO, Visakhapatnam from the Villagers of Tanam, Parawada (M), Visakhapatnam on open burning of hazardous waste material and causing odour nuisance in the area. The Committee also noted the non-compliance of the
consent conditions. The EE, RO, Visakhapatnam has informed that a scrap vendor has stored about 200 Nos. of 200 LT HDPE empty drums on open ground and about 100 no. of black bags were stored openly. The bags were opened and observed that the bags are containing nose masks, head caps, gloves, empty vials and shredded QA documents. On enquiry, the scrap vendor informed that the material belongs to Sri Srinu, who is a scrap vendor from Hyderabad and storing the material in his godown. After verification of the bags randomly, labels of M/s. Gland Pharma Ltd., Unit – 2, VSEZ Duvvada were observed. The scrap vendor informed that the material belongs to M/s. Gland Pharma. The representative of the industry informed that three different vendors for disposal of waste generated at the plant i.e M/s. Ramky for disposal of hazardous waste generated during process. This includes crushed glass waste, hazardous product waste, PPEs used during process etc., M/s. Mohan enterprises, is an scrap vendor to whom they sell solid non-hazardous waste like Cardboard boxes, paper waste and other general waste, M/s. Maridi Eco Industries, to whom they dispose Bio medical waste like Microbial monitoring media. They informed that they regularly segregate the hazardous waste and non-hazardous waste and store them in designated area. After accumulation of sufficient quantity (monthly once or twice) they send the non-haz waste for disposal. They also informed that they send all the hazardous waste generated to TSDF in the month of December, 2017. Non-hazardous solid waste was sent to M/s. Mohan Enterprises on 18th of December, which included the Card board boxes and other office waste (like Shredded papers, PPEs masks & masks used in office areas), but there was intention to the company to dispose the waste for open burning.

The after detailed review the committee recommended to issue the directions. The Board is hereby issue the following directions under Sec.33 (A) of Water (Prevention and Control of Pollution) Amendment Act, 1988 and under Sec.31 (A) of Air (Prevention & Control of Pollution) Amendment Act, 1987:

1. **The industry shall segregate wastes at source and shall dispose all types of solid waste (except biomedical waste) to TSDF, Parawada henceforth. There shall not be any further disposal of solid waste to unauthorized agencies/ individuals to prevent re-occurrence in indulging in open burning of solid waste.**

2. **The industry shall strictly maintain records on generation and disposal of off-specified products; rejected & expired drug materials as the unit is dealing with oncology drug formulations.**

3. **The industry shall submit the Bank Guarantee of Rs.2Lakhs within 15 days for period of one year validity towards compliance of Board directions.**

4. **The industry shall ensure continuous compliance of conditions issued in the CFO and HWA order.**

You are hereby directed to note that, should you violate any one of the directions mentioned above, action will be initiated under Sec.33 (A) of Water (Prevention & Control of Pollution) Amendment Act, 1988 and Sec.31(A) of Air (Prevention & Control of Pollution) Amendment Act, 1987 without any further notice, in the interest of Public Health and Environment.

*This Order comes into effect from today i.e., 22.01.2018.*

Sd/-
MEMBER SECRETARY

To
M/s. Gland Pharma (Formulation),
Unit-II, Block-C, Phase-I,
VSEZ, Duvvada,
Visakhapatnam.

Copy to:
1. The Joint Chief Environmental Engineer, Zonal Office, Visakhapatnam for information and necessary action.
2. The Environmental Engineer, Regional Office, Visakhapatnam with a direction for information and necessary action.

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

JOINT CHIEF ENVIRONMENTAL ENGINEER
UH-II