UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

Mr. Shanin Specter, Esq.
Mr. Thomas E. Bosworth, Esq
Klein & Specter, PC
1525 Locust Street
Philadelphia, Pennsylvania 19102

Dear Mr. Specter and Mr. Bosworth:

The Environmental Protection Agency (EPA) received your letter dated May 4, 2021 concerning ethylene oxide (EtO) emissions and health concerns from the B. Braun facility in Allentown, Pennsylvania. EPA identified EtO as a human carcinogen and released the 2014 National Air Toxics Assessment (NATA) in August 2018, that estimated possible risk exposures to communities. The 2014 NATA is a screening analysis that is used to identify potential areas of concern. It is important to note that additional local assessment is warranted.

EPA has operated on a two-prong strategy to both explore additional regulatory options for EtO and gather and refine the analysis for high risk facilities emitting EtO. At this time, EPA will be proposing to revise the EtO Commercial Sterilizers Maximum Achievable Control Technology (MACT) standard this year. EPA has worked with state and local agencies to gather emissions data, permitting data, inspection data to help refine the estimates since the 2014 assessment. The updated information will be used in the EtO Commercial Sterilizers proposal.

The B. Braun facility in Allentown was identified as a high-risk facility based on 2014 data. There has been changes at B. Braun since the release of NATA in 2018. The facility voluntarily installed a new control device and commenced operation in September 2020. A stack test was performed on the control system in December 2020 and the reported results showed greater than 99% compliance. This additional information has been submitted to the EtO Commercial Sterilizers MACT team for evaluation.

EPA is working to help reduce EtO emissions and mitigate risk exposures to communities. EPA has a website [HYPERLINK "https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide"], which contain updated information on various regulatory actions as well as quarterly reports from regional offices regarding activities for high risk facilities [HYPERLINK "https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/inspector-general-follow-ethylene-oxide-0"]. Should you have additional questions, please contact Ms. Cristina Fernandez, Director, Air and Radiation Division, at (215) 814-2178.

Sincerely,

Diana Esher
Acting Regional Administrator

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