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Via Electronic Mail

March 31, 2025

United States Environmental Protection Agency
Office of Air and Radiation
1200 Pennsylvania Avenue, N.W.,
Washington, DC 20460
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CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION – EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

Re: Presidential Exemption Request: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24090 (Apr. 5, 2024), for B. Braun US. Device Manufacturing LLC's Allentown Facility

To Whom it May Concern:

B. Braun US Device Manufacturing LLC[1] ("BB Device" or the "Company") requests a Clean Air Act Section 112 Presidential Exemption. BB Device respectfully requests President Trump exercise his authority under section 112(i)(4) of the Clean Air Act ("CAA") to grant BB Device a two-year exemption to comply with the requirements of the EPA's final rule "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review"[2] (hereafter the "2024 Rule"). BB Device requests a two-year exemption from all compliance deadlines for the 2024 Rule including: (i) all standards and requirements related to CAA Section 112(f); and (ii) all standards and requirements related to CAA Section 112(d). BB Device requests this exemption for its medical device manufacturing facility located at 901 Marcon Blvd., Allentown PA 18109 (the "Allentown Manufacturing Facility").

BB Device takes its commitments to the environment seriously and has invested significant time, energy, and resources to timely comply with the 2024 Rule. BB Device has made significant progress towards that goal. However, the lack of availability of

[1] Prior to May 1, 2024, the Allentown Manufacturing Facility was owned and operated by B. Braun Medical, Inc. Due to corporate restructuring, as of May 1, 2024, the Allentown Manufacturing Facility is owned and operated by B. Braun US Device Manufacturing LLC.
[2] 89 Fed. Reg. 24090 (Apr. 5, 2024).

proven technology needed to comply with the current version of the 2024 Rule, related national security issues as a result of the impact on supply of sterilized medical products, and the EPA's recent decision to reconsider the 2024 Rule "in its entirety", make a two-year compliance exemption necessary and appropriate.

I. The Current 2024 Rule Requires Technology in Limited Supply or Unavailable

The 2024 Rule's current standards present significant challenges regarding available technology. BB Device, and its predecessor B. Braun Medical Inc., have spent decades investing in ethylene oxide abatement equipment for the Allentown Manufacturing Facility that meets or exceeds EPA standards. Consistent with our history of regulatory compliance and safety, BB Device worked hard and invested significant resources to put itself in a position to comply with many of the technology requirements set forth in the 2024 Rule. Recently, between 2020-2022, BB Device invested millions in new abatement and monitoring equipment. Even with all of BB Device's preparations, there are real issues with the availability of certain technologies.

Practically, even if the necessary technologies exist, they are in limited supply. The 2024 Rule sets new destruction removal efficiency standards ("DRE") for many aspects of the sterilization process, and the Rule changes how DREs are calculated—requiring sterilizers to achieve these DREs on a thirty-day rolling average. If the technology does exist to comply with these requirements, it is scarce, and requires facility redesigns, equipment customization, installation, testing, and validation. Considering the number of sterilization facilities across the country that will need the same upgrades, many will not be able to meet the current deadlines.

There are also questions about whether any currently available technology can achieve the DRE requirements in the 2024 Rule. By way of example, in 2020, BB Device installed a customized EtO abatement system that controls its sterilization chamber vents and has a proven stack test DRE of more than 99.9%. Although BB Device believes the system may be able to achieve the 99.99% DRE standard under the 2024 Rule through innovations and adjustments, that has not been proven. Achieving the 2024 Rule's required DRE over a 30-day average raises concerns and questions for all of its sterilization vents.

If the necessary technology to bring sterilizers in compliance with the 2024 Rule is unavailable, there are no proven alternative sterilization methods to sterilize all medical devices. The FDA[3] acknowledged: "[f]or many medical devices, sterilization

[3] FDA, *Sterilization for Medical Devices* available at https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#:~:text=Medical%20devices%20are%20sterilized%20in,acid%2C%20and%20nitrogen%20dioxide) (last updated: November 26, 2024); *see also* EPA, *Additional Questions About Ethylene Oxide*, available at https://www.epa.gov/hazardous-air-pollutants-ethylene-

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with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process." Even if an alternative sterilization method is identified, it will take years to test, install, and scale that process. Ex. 4 CBI

Ex. 4 CBI

II. Without an Exemption, Sterilizers May be Forced to Shut Down, Which Would Eliminate Necessary Medical Devices From the Market and Threaten National Security

Any facility that cannot comply with the 2024 Rule's deadlines would need to shut down its sterilization operations, which would place national security at risk because it would reduce the number of life-saving medical devices available in the US Market.

BB Device manufactures crucial life-saving devices at the Allentown Manufacturing Facility for patients throughout the country. As just one example, BB Device is a U.S. Market leader in regional anesthesia.[4] If the Allentown Manufacturing Facility was no longer able to sterilize its epidural kits, it would create a severe nationwide shortage. Medical supply shortages can be sudden and unexpected, such as when Hurricane Helene damaged a manufacturing facility in the fall of 2024, which led to nationwide shortages for intravenous products.[5] Shortages place the public at risk and add an additional layer of uncertainty to healthcare. Ex. 4 CBI

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oxide/additional-questions-about-ethylene-oxide-eto#:~:text=As%20of%20now%2C%20EtO%20is,to%20patients%2C%20especially%20during%20surgery (last updated January 14, 2025).

[4] 2020Q4 All Regional Anesthesia Products: Total Market HC & OPM Dollars (GHX, IQVIA [MDSA] & B. Braun Data On File)

[5] FDA, *Hurricane Helene: Baxter's Manufacturing Recovery in North Carolina*, available at https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina (last updated March 18, 2025).

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If the Allentown Manufacturing Facility could not sterilize and ship its products, other manufacturers do not have the capacity to make up the shortfall and would need to decrease the manufacture of other products made in the ordinary course of business. Further, BB Device would not be able to simply move all of its products to contract sterilization overnight. Contract sterilizers do not have unlimited capacity, and if multiple manufacturers have their sterilization operations shut down because of the 2024 Rule, it would compound those capacity constraints.

III. EPA's Reconsideration of the 2024 Rule

The EPA announced its intent to reconsider the 2024 Rule "in its entirety", and stated that "some or all" provisions of the Rule may be revised. On March 25, 2025, the EPA filed a brief with the Court of Appeals for the District of Columbia, in which the EPA told the Court that "EPA has decided to reconsider the 2024 Rule ***in its entirety***."[6] The EPA explained that it "anticipates its reconsideration of the Rule will involve further rulemaking that could revise or rescind ***some or all of the portions of the Rule***."[7]. In support of its position, the EPA included as an exhibit a March 21, 2025, letter from Abigale Tardif, Principal Deputy Assistant Administrator of the Office of Air and Radiation that stated the EPA was reconsidering the 2024 Rule[8], including its authority and decision to undertake a second residual risk review and the resulting risk standards. The EPA's stated goal is to complete its reconsideration by March 2026.[9]

With the entire 2024 Rule under reconsideration, it is possible the EPA will "revise or rescind" some or "all" aspects of the 2024 Rule. Under those circumstances a two-year compliance exemption is both appropriate and necessary. Until the reconsideration process is complete it will be impossible for any sterilizer to ensure its operations comply with any changes or revisions that may be made to the Rule.

IV. Confidentiality

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[6] *See* Petitioner's Br., P. 10, *Ethylene Oxide Sterilization Association et al. v. U.S. Environmental Protection Agency et al.*, (D.C. Cir., 2025) (emphasis added).
[7] *Id.* At 4-5 (emphasis added).
[8] *See* EPA Letter to EOSA (Mar. 21, 2025).
[9] *Id.* at 9.

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For all these reasons, BB Device respectfully requests a two-year exemption from all compliance deadlines set forth in the 2024 Rule. Please do not hesitate to contact me with any questions, or if any further information is needed.

Kind Regards,

Mike Bartholomew
President
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