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December 14, 2021

Mr. Rupesh Patel
Air Quality Program Manager
Department of Environmental Quality
33 North Stone Avenue, Suite 700
Tucson, Arizona 85701

Subject: BD Class II Permit – Public Comments

Dear Mr. Patel:

BD appreciates PDEQ's thorough review of the Class II permit application and a robust public review process. BD would like to use this opportunity to reiterate our commitment to constructing and operating a state-of-the-art ethylene oxide sterilization facility in Tucson, Arizona.

As detailed in the draft air permit and technical support document (TSD), the proposed facility will be one of the most effectively controlled ethylene oxide (EO) sterilization facilities in the United States, meeting or exceeding applicable federal, state, and local Environmental, Health, and Safety requirements. The Lesni Catalytic Oxidation system will have a control efficiency greater than 99 percent, exceeding the requirement identified in 40 CFR Part 63 Subpart O. Additionally, to address potential fugitive emissions from the process areas and post-sterile warehouse, BD is proposing installation of state-of-the-art voluntary fugitive controls (AAT drybeds).

Monitoring and record keeping to ensure compliance with the permit conditions will exceed current federal requirements. Monitoring reports detailing actual EO emissions from the facility will be submitted to PDEQ in accordance with the permit requirements.

In addition to EO's broad use in a variety of products, such as lubricants and automotive fluids, detergents, adhesives, inks, and synthetic materials (eg. polyester), EO is an important and widely used sterilant. The sterilization method is determined through a rigorous design process which includes review of material compatibility, product and packaging functionality, biocompatibility, and product shelf life, in accordance with the requirements set forth by the United States Food and Drug Administration (FDA) and as outlined in consensus standards such as ISO/AAMI 11135-2015.

Sterilization by EO allows for the widest range of material compatibility. Many single use devices (surgical devices, syringes, specialty catheters, pharmaceutical devices, surgical kits, etc) are sterilized with EO because they are too sensitive to be sterilized by any other method. Other sterilization modalities such as steam or radiation may cause undesirable effects such as product discoloration, embrittlement, impairment of product functionality, or loss of packaging integrity.

The effects of steam and radiation on anti-microbial coatings or drug products may preclude use of either method for sterilization. Multi-component kits such as surgical kits may contain one or more devices which are sensitive to heat or radiation which also prevent the use of these methods for kitted products. Additionally, novel sterilization modalities have not been proven efficacious, or economically viable, at the scale needed to support the global demand for sterile medical devices.

Thank you for the opportunity to submit information during this public review process. We look forward to timely issuance of the permit to ensure we are able meet increasing demand for life saving medical technology as part of our commitment to public health and our continued response to the coronavirus pandemic.

Sincerely,



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