**Information On BD’s Use of Ethylene Oxide**

Medical product sterilization is a critical step in the manufacturing process that is required by the FDA for all medical device manufacturers to protect patients from the risks of infectious diseases caused by bacteria, viruses and fungi. BD is committed to ensure our medical sterilization facilities are operating in a safe and responsible manner, and our facility has programs and procedures in place to ensure compliance with the Clean Air Act. The levels of ethylene oxide (EtO) around the BD facility are similar to levels found in ambient air at EPA monitoring locations across the US, even where there are no sterilization facilities present, including rural locations. BD was one of the first medical technology companies to innovate new capture and control technologies to further reduce EtO emissions from our sterilization facilities. The first systems were installed in our facilities in Georgia and after they proved to be effective, BD initiated the installation of similar systems at all of our EtO sterilization facilities nationwide, with the Columbus facility coming online next year. However, even before the new technologies are installed, the levels of EtO around the BD facility are similar to levels found in ambient air at EPA monitoring locations across the U.S., even where there are no sterilization facilities present and in rural locations.

BD’s Columbus-East facility is a significant producer of syringes that pharmaceutical companies use to deliver prefilled drugs and vaccines for patients and is also one of the largest and most sophisticated plastic molding facilities in the world that produces billions of components for numerous products that are critical for patient care. BD’s Columbus – West facility is one of the world’s largest producers of needles and saline flush syringes, as well as other products that are essential to patient care. BD employs 2,200 people in Columbus and more than 3,000 across Nebraska. The company has been a responsible member and significant contributor of the Columbus community for more than 70 years, and our facility has programs and procedures in place to ensure compliance with all applicable permits and regulations, and it operates safely for our employees and the community.

**Additional Information About BD’s Facility in Columbus**

Ensuring the safety of our employees and communities is a top priority for BD. Because of this commitment to safety, BD uses the best available emission control technology in the industry. BD’s emission control technology achieves >99.9% destruction of EtO, significantly greater than the 99% required under the Clean Air Act. To illustrate the difference between the requirement and BD’s technology, for every 100 lbs of EtO used, the Clean Air Act would allow 1 pound of emissions from the control equipment. However, for every 100 lbs of EtO used in Columbus, BD’s technology reduces stack emissions to less than an ounce. In other words, BD’s technology is 20 times more effective at reducing EtO emissions than what is currently required by the Clean Air Act. BD’s facility in Columbus has programs and procedures in place to ensure compliance with all applicable regulatory requirements, including regulations from EPA, OSHA, Nebraska DEE, FDA and multiple permits.

Following final packaging of the medical products produced in Columbus, and after the sterilization process is completed, products are stored in a warehouse section of the facility. Those products have been aerated during the sterilization process to ensure any residual EtO remaining in the packaging is lowered to only trace amounts. BD complies with FDA regulations to ensure EtO residual in its products are at or below the limits set by FDA ensuring patient safety. In recent years, BD has collaborated with various agencies and industry partners in conducting research to better understand the amount of residual EtO that is emitted from sterile products. BD is on the leading edge in the development of new methods of EtO capture and control technologies to significantly reduce these emissions. As part of this, BD is voluntarily investing $[18 million to construct a new building and install a state-of-the-art capture and treatment system for residual EtO emissions  in Columbus, which will be operational by the end of next year. This investment is a voluntary action that BD has proactively taken and is not required by EPA or Nebraska DEE.

It is also important to understand that the recent webinar from EPA was based on the agency’s recently updated view of EtO emissions and more stringent risk assessments, particularly aimed at sterilization facilities. The amount of EtO that U.S. EPA used as its screening value for the new risk assessments is 10 to 20 times lower than what is found in ambient air measurements in areas across the country where there is no industrial source of EtO. While EPA is stating that some areas immediately adjacent to the facility show emissions that are currently above its new risk threshold, after the new controls are installed by the end of next year, emissions will be within the US EPA’s revised and more stringent range of acceptable risk level. But even before the controls are installed, the levels of EtO around the BD facility are similar to levels found in ambient air at EPA monitoring locations, even where there are no sterilization facilities present.