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December 20, 2019

VIA ELECTRONIC TRANSMISSION

Karen Hays, via email
Chief, Air Protection Branch
Georgia Environmental Protection Division
4244 International Parkway, Suite 120
Atlanta, GA 30345

Re: **BD Response to EPD December 18, 2019 Letter Providing Notice of Alleged Air Quality Violations at BD Global Distribution Center, Covington, Georgia (GDC)**

Dear Ms. Hays,

As requested, BD is providing this response to your December 18, 2019 letter which suggests that, because of certain ethylene oxide (EtO) emissions from medical device product inventory stored in the GDC, BD is required to apply for an EPD air quality permit for the GDC. As EPD knows from conversations this week, BD takes its environmental, health and safety compliance obligations very seriously.

In a good faith attempt to resolve these issues voluntarily, BD agrees to stop placing medical device products sterilized using ethylene oxide in the GDC from December 23, 2019 at 5PM to midnight January 6, 2020. In addition, BD agrees that, after January 6, 2020, it will receive for storage medical device products sterilized with ethylene oxide in the GDC only if those products have been sterilized in accordance with the 24-hour aeration cycle time previously agreed to by BD and EPD.

As for responses to the ten specific technical questions raised in your letter, BD's technical teams are currently collecting additional data and information to answer those questions. In accordance with your request, BD will submit a response to those specific items on or before 5 PM December 23, 2019.

With respect to other requests in your letter, BD agrees that it will initiate weekly indoor air monitoring and outdoor fence line monitoring for EtO at the GDC, and BD will continue with this monitoring until the air quality permit for the GDC is issued by EPD. As we have discussed with EPD, we are attempting to locate an adequate supply of Summa canisters to complete the additional air quality monitoring. Our engineering teams will be coordinating with EPD to finalize details of the air quality monitoring.

For years, long before any discussions of possible fugitive product emissions at the GDC between BD and EPD, BD has been conducting exposure monitoring to ensure the GDC is a safe place to work. In the most recent industrial hygiene monitoring at the GDC, average EtO concentrations were about 65% below the permissible exposure limits set by the Occupational Safety and Health Administration (OSHA), which regulates EtO levels inside similar facilities. As explained in BD's December 15 submission to EPD, air monitoring testing results from outdoor sampling locations also confirm that EtO levels in ambient air outside of the GDC are in line with background EtO levels found by both EPD and EPA at air monitoring sites in Georgia and across the country where there are no industrial sources of EtO.

In terms of EPD's final request, BD agrees to submit an air quality permit application to EPD within the next 45 days to address air quality fugitive emissions from sterilized medical devices stored at the GDC. At this point, we know of no current U.S. Environmental Protection Agency (EPA) or industry standard for calculating fugitive emissions from a medical device distribution facility storing medical devices sterilized with EtO, and EPA is currently researching this very issue in the context of EtO. We are also not aware of any facility in the country like the GDC that requires a permit for purely fugitive product emissions. We expect to work closely with EPD to develop a workable system at the GDC for these challenging technical issues.

Given the nature of the operations, our medical device sterilization facilities in Covington and Madison have been regulated extensively by the FDA since they began operating. In fact, the EtO sterilization cycles implemented at Covington and Madison are part of the product registrations we hold with FDA.

As we move forward, and after our technical teams develop workable solutions, we agree to amend the current Judicial Consent Order and address the GDC requirements proposed in your letter. In agreeing to these voluntary actions and completing this work, we hope to avoid shutdowns that would create negative, life-threatening patient impacts in Georgia and across the U.S. Thank you for your cooperation as we work through these novel regulatory issues.

Sincerely

Ellen Kondracki

Vice President, Sustainability
and Environment, Health & Safety

cc: Peggy Eckrote, State of Georgia, Office of the Attorney General
Robin Leigh, State of Georgia, Office of the Attorney General
Michelle Quinn, BD
Douglas Henderson, King & Spalding
Les Oakes, King & Spalding