

IN THE SUPERIOR COURT OF NEWTON COUNTY
STATE OF GEORGIA

RICHARD E. DUNN, DIRECTOR,
ENVIRONMENTAL PROTECTION
DIVISION, GEORGIA DEPARTMENT OF
NATURAL RESOURCES,

Plaintiff,

v.

BECTON, DICKINSON and COMPANY,

Defendant.

CIVIL ACTION FILE NO.

SUCV2019002219-1

FILED IN OFFICE
CLERK OF SUPERIOR COURT
NEWTON COUNTY, GEORGIA
SUCV2019002219
EUGENE M. BENTON
MAR 25, 2020 10:05 AM


Linda D. Hays, Clerk
Newton County, Georgia

SECOND AMENDMENT TO CONSENT ORDER

Plaintiff Richard E. Dunn, Director, Environmental Protection Division, Georgia Department of Natural Resources (“EPD”) and Defendant Becton, Dickinson and Company (“BD”) (the “Parties”) file this Second Amendment to the Consent Order entered on October 28, 2019 (“Consent Order”) and First Amendment to Consent Order entered on January 15, 2020 as follows:

WHEREAS, in the Consent Order and First Amendment to Consent Order entered by this Court, BD agreed to cease certain activities, conduct additional testing, submit additional engineering and regulatory documentation, implement process verification processes and procedures, and complete numerous activities by dates certain related to the medical device sterilization process, emissions and activities at the BD Covington facility and at other storage locations in Covington;

WHEREAS, the United States and the World have been dealing with the pandemic caused by COVID-19, which has led to a shortage of particular medical devices that BD

sterilizes at the Covington facility, as indicated by the March 20, 2020 letter from the U.S. Food and Drug Administration (“FDA”);

WHEREAS, the Parties have agreed to amend the Consent Order and First Amendment to Consent Order as to conditions for the Covington facility and the Global Distribution Center (“GDC”) once certain requirements are met;

THEREFORE, upon stipulation and full agreement of the Parties, it is hereby ORDERED that:

The Consent Order executed by this Court on October 28, 2019, and the First Amendment to Consent Order executed by this Court on January 15, 2020, remain final and binding on all Parties, except as to the specific modifications agreed upon in the Attachment to this Second Amendment to Consent Order.

In the Second Amendment to Consent Order, the Parties agree to and shall implement and complete and take other actions as set forth in Attachment to this Second Amendment to Consent Order, which is incorporated into and made a part of this Second Amendment to Consent Order. Any act required to be done under the Attachment shall be enforceable as an order of this Court.

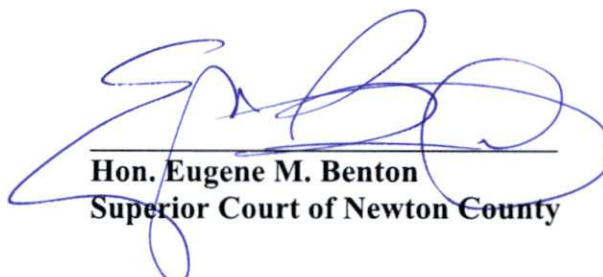
BD agrees to perform all requirements contained in the Attachment. In the event a Party disputes any aspect of compliance with this Second Amendment to Consent Order, the Parties shall first, before bringing any dispute to this Court, attempt to resolve the dispute promptly in good faith between representatives of the Parties with authority to settle the dispute.

The Second Amendment to Consent Order may be modified only upon approval of the Court and the Court retains jurisdiction over this case until December 31, 2020, for the purpose of amendments or enforcement of any violations of the Consent Order, First Amendment, or Second Amendment.

Except as specifically set forth in this Second Amendment to Consent Order, the Consent Order and First Amendment to Consent Order shall remain valid and effective.

IT IS SO ORDERED.

This 25 day of March, 2020.



Hon. Eugene M. Benton
Superior Court of Newton County

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

DATED: March 25, 2020

STATE OF GEORGIA

/s/ Margaret Kemmerly Eckrote
Margaret Kemmerly Eckrote
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DATED: March 25, 2020

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Counsel for Defendant

Becton, Dickinson and Company

Attachment to Second Amendment to Consent Order

Attachment to Second Amendment to Consent Order

Effective immediately, the following amendments to the Consent Order and First Amendment to Consent Order will be in effect until 14 days after the Declaration of Public Health State of Emergency for Coronavirus is no longer in effect. After that date, the Conditions in the Consent Order and First Amendment to Consent Order control until final permits are issued.

1. Condition 4 of the Consent Order is hereby amended to read as follows:
Effective immediately, BD shall reduce fugitive emissions in Covington in accordance with this paragraph. BD will conduct aeration phases of the production process to no fewer than 20 hours per lot of heated aeration and, once operational, 24 hours of dry bed aeration in the Work in Progress (WIP) portion of the Covington facility, and limit the number of product lots sterilized at Covington to an average of 825 product lots per month calculated on a rolling 90-day average as illustrated in Condition 8. For purposes of this Order, a "product lot" is eight pallets of product. All ethylene oxide from heated aeration will continue to be captured and controlled by the Regenerative Thermal Oxidizer ("RTO") and fugitive emissions from the BD Covington WIP portion of the facility will be captured and controlled by the fugitive emissions control system upgrades, once operational, as described in the permit application for the BD Covington facility.
2. Condition 8 of the Consent Order is hereby amended to read as follows:
No later than Monday, October 28, 2019, BD will submit to EPD an illustration of BD's mass balance method used for calculating fugitive emissions, i.e., the amount of ethylene oxide used in the process less the amount of ethylene oxide captured and controlled by the RTO equals the calculated amount of ethylene oxide fugitive emissions. BD shall have a third-party engineer verify the correct application of this method, including documentation of the engineering calculations used to determine the impact of BD's operational changes on fugitive ethylene oxide emissions at Covington. BD shall immediately implement these changes when sterilization operations resume on November 7, 2019 and shall submit monthly documentation to EPD confirming ethylene oxide fugitive emissions. For illustration purposes, to calculate the average number of product lots sterilized at Covington for purposes of calculating the throughput limitation of 825 lots per month referenced in Condition 4 over any rolling 90-day period, one would take the total number of lots sterilized at Covington for each of the three previous months, add them together and divide that number by three to arrive at the average monthly number of lots sterilized at Covington.
3. Condition 13 of the Consent Order is hereby amended to read as follows:
In accordance with an EPD approved plan, BD shall conduct an initial demonstration of the fugitive emissions control system upgrades proposed in the permit application for the BD Covington facility no later than April 15, 2020. BD will use commercially reasonable efforts to accelerate this timeline.

4. Condition 15 of the Consent Order is hereby amended to read as follows:
BD shall limit the number of product lots at the BD Madison facility to no greater than the average of 685 product lots per month calculated on a rolling 90-day average as illustrated in Condition 8 until the final permit for the BD Covington facility is issued.
5. Condition 16 of the Consent Order is hereby amended to read as follows:
BD shall submit weekly reports of the daily number of lots sterilized, ethylene oxide usage, ethylene oxide destructed through the RTO, and sterilization cycle reports to demonstrate 20 hours per lot of heated aeration and, once operational, 24 hours of dry bed aeration in the Work in Progress (WIP) portion of the Covington facility and 24 hours of aeration time at the Madison facility.
6. Condition 2(d) of the First Amendment to Consent Order is hereby amended as follows:
On or before January 13, 2020, BD shall cease accepting Foley Catheter Procedural Trays at the GDC. Once BD ceases accepting Foley Catheter Procedural Trays at the GDC, BD shall inventory the number of Foley Catheter Procedural Trays stored at the GDC and shall provide certification of that number to EPD on or before January 13, 2020. BD shall be permitted to store at the GDC individually packaged and sterilized Foley strip catheters from the BD Covington facility that have been subject to at least 20 hours per lot of heated aeration and, once operational, 24 hours of dry bed aeration in the Work in Progress (WIP) portion of the Covington facility. BD shall be permitted to store at the GDC individually packaged and sterilized Foley strip catheters from other facilities that have been subject to at least 24 hours of aeration.
7. Condition 2(j) of the First Amendment to Consent Order is hereby amended as follows:
By December 31, 2020, BD shall remove all sterilized products stored in the GDC that were not subject to 24 hours of aeration time in an aeration chamber prior to being stored at the GDC. BD shall accomplish the removal and provide certification to EPD as follows:
 - (1) BD shall complete the removal of 50% of the products aerated for less than 24 hours from the GDC by April 1, 2020, and shall certify that it has accomplished the removal to EPD on April 1, 2020,
 - (2) BD shall complete the removal of an additional 25% (for a total of 75%) of the products aerated for less than 24 hours from the GDC by October 1, 2020, and shall certify that it has accomplished the removal to EPD on October 1, 2020, and
 - (3) BD shall complete the removal of an additional 25% (for a total of 100%) of the products aerated for less than 24 hours from the GDC by December 31, 2020, and shall certify that it has accomplished the removal to EPD by December 31, 2020.

All medical device products sterilized at the BD Covington facility pursuant to the procedures outlined in this Second Amendment to Consent Order are exempt from the removal requirements in Condition 2(j).

8. Condition 3 of the First Amendment to Consent Order is hereby amended as follows:
After January 6, 2020, BD shall not send medical device product to the GDC from the BD Covington facility unless it has been subject to at least 20 hours per lot of heated aeration and, once operational, 24 hours of dry bed aeration in the Work in Progress (WIP) portion of the Covington facility. All other medical device products sent to the GDC from other facilities must have been aerated for at least 24 hours.

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BECTON, DICKINSON and COMPANY,

Defendant.

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* Civil Action File Number:
* 2019-CV-2219-1
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CERTIFICATE OF SERVICE

This is to certify that I have this day served a true and correct copy of the foregoing **SECOND AMENDMENT TO CONSENT ORDER** either by facsimile transmittal, electronic mail and/or by mailing a copy of same in the United States Postal System with adequate postage affixed thereon to insure delivery, addressed as follows:

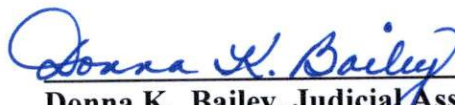
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This 25th day of March, 2020.



Donna K. Bailey, Judicial Assistant
to the Honorable Judge Eugene M. Benton