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October 10, 2019

VIA EMAIL AND HAND DELIVERY

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Re: Continued Suspension of Sterilization Services and Requirement for New Certificate of Occupancy

Dear Mr. Johnson,

Thank you, Mr. Dawe, Mr. Gobble, and other Cobb County representatives for meeting with us on October 1. I write in response to your October 1, 2019 letter provided to us during that meeting.

Cobb County approved and issued a building permit for the construction of the additional emission controls at Sterigenics' Cobb County facility on August 15, 2019 (the "Building Permit"). See **Exhibit A**.¹ The County's review and approval of that Building Permit was under an "Industrial High Hazard" occupancy classification, as the Building Permit expressly states. These are uncontested facts the County continues to ignore. The County's claim in your letter that Sterigenics "is not permitted to engage in construction or sterilization operations at its Cobb County facility" is inaccurate. Sterigenics has a vested right under Georgia law to complete this construction under the Building Permit and to occupy its facility upon completion.

The County's contention that "Sterigenics currently maintains a Certificate Occupancy for only 'Storage'" is demonstrably untrue. What the County continues to tell the public in that regard also is difficult to understand. As we explained during our meeting, and as shown by County records, the Certificate of Occupancy for "Storage" referenced by the County is a July 25, 2007 Certificate of Occupancy for the adjacent *warehouse space* (identified as 2971 Olympic Industrial Drive, Suite D) Sterigenics began leasing in 2007. See **Exhibit B**. That warehouse space is used for the storage and shipment of medical products after they are sterilized. As the County should

¹ The line and box notations in the exhibits to this letter are mine for your attention.

know from its records and many inspections of the facility over the years, no storage or use of ethylene oxide for sterilization operations occurs in that warehouse.

Rather, Sterigenics' use and storage of ethylene oxide for sterilization operations is in a different area of the facility. A separate Certificate of Occupancy (No. 0961) readily found in the County's records you provided to us applies to that area of the facility. That April 25, 1984 Certificate of Occupancy (attached hereto as **Exhibit C**²) expressly certifies that this area is an "Industrial" occupancy.³ The County plainly recognized this occupancy when it issued the Building Permit in August 2019 for Sterigenics to install the additional emissions controls.

Further, the County's suggestion that it was unaware of Sterigenics' occupancy and use of ethylene oxide in its sterilization operations at the facility is belied by the facts and County records. Indeed, the County has recognized Sterigenics' sterilization facility as an Industrial and High Hazard occupancy for many years. That fact is reflected by numerous records in the County's files, including those attached hereto as **Exhibits C** and **D**.⁴ Moreover, the County Fire Department has toured and inspected the facility multiple times over the years. *See, for example, Exhibit E.* In fact, the County's Fire Department toured the facility with Sterigenics shortly before the County issued the Building Permit. The County Fire Department even participated in an emergency response drill focused on a mock ethylene oxide leak in March 2010, and recently asked about participating in a similar drill at the facility in the future. The County cannot deny its knowledge of Sterigenics' legitimate, longstanding occupancy at the facility.

The County's positions are not only unfounded, they serve no public interest. The work Sterigenics seeks to complete at the facility under the Building Permit is the voluntary installation of emissions control technology that provides the greatest reduction in ethylene oxide emissions available. This technology would further reduce ethylene oxide emissions at the facility below their already safe levels with an efficiency of greater than 99.99%. There is no legitimate reason for the County to prevent Sterigenics from completing these modifications.

² Sterigenics was formerly known as Griffith Laboratories and Griffith Micro Science, Inc.

³ Regardless of the current occupancy nomenclature in the County's building code, the existence of Sterigenics' sterilization operations at the facility (since the early 1970s) long before the County's adoption of that code entitles it to continue its use of the facility without change, as a matter of law. Sterigenics is not required to have a "new" certificate of occupancy from the County in order to do so. Moreover, as the Fire Marshal determined when approving the Building Permit, Sterigenics' work under the Building Permit is a "REMODEL – minor construction," not a substantial renovation the County secondarily claims requires a new certificate of occupancy upon completion. *See Exhibit A.* Regardless, Sterigenics' vested right to use and occupy the facility upon completing its work under the Building Permit cannot be impeded by any alleged requirement that the Fire Marshal issue a certificate of occupancy after the work is completed.

⁴ For a period, the location of Sterigenics' sterilization facility was identified as 2973 Olympic Industrial Drive. The County subsequently consolidated the areas including Sterigenics' sterilization facility and adjacent warehouse space into one address, 2971 Olympic Industrial Drive, S.E., Suite 116, in or around 2015.

Brian Johnson, Esq.

October 10, 2019

Page 3

Moreover, the County's actions are jeopardizing access to medical treatment and putting medical patients at risk. Those include patients in Cobb County. More than a million critical and life-saving medical products are sterilized at Sterigenics' facility each day. If these products are not sterilized in accordance with FDA requirements, they cannot be used, and vital medical procedures are at risk of not occurring. The FDA itself has recognized this concern. See: <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#news>. This also threatens to put medical device manufacturers, including Georgia companies, out of business, because medical providers cannot use (and, therefore, will not purchase) their products unless they are properly sterilized.

Sterigenics requests that the County allow it to complete its work under the Building Permit and resume its operations at the facility without further delay.⁵ As we have tried over the past few weeks, Sterigenics will cooperate with the County in any legitimate and pertinent way related to the remaining installation of the additional emissions controls in order to finish the work and recommence its operations. If, however, the County continues to unjustifiably prohibit Sterigenics' work and use of its facility, Sterigenics will have no choice but to pursue the legal and equitable relief necessary to protect itself, its customers, medical providers and patients from the irreparable harm the County is causing.

Regards,



W. Clay Massey

Attachments

Cc: Dan Diffley, Esq.
H. William Rowling, Esq., Cobb County Attorney (via email)
Nick Dawe, Cobb County Fire Marshal (via email)
Kevin Gobble, Cobb County Chief Building Officer (via email)

⁵ The "revised plans" your letter references are not a reason to further delay Sterigenics' remaining installation of the additional emissions controls under the issued Building Permit. Those drawings simply reflect the removal or addition of items unrelated to the additional emissions controls to be completed under the Building Permit, or miscellaneous modifications to address certain existing conditions at the building discovered during construction. The County's claim that those items are "complex" and require a "third-party technical expert" review in order to delay Sterigenics' remaining work under the Building Permit is simply not true.