

CIVITAS THERAPEUTICS, INC.

FACT SHEET - November 30, 2020

Who they are:

Civitas Therapeutics, Inc. (Civitas) operates a biopharmaceutical facility at 190 Everett Avenue, Chelsea, MA. Activities at the Chelsea facility have been limited to research and development and small-scale manufacturing. Civitas was acquired by another biopharmaceutical company, Acorda Therapeutics, Inc., in 2014.

What they manufacture:

Civitas specializes in the development and manufacturing of neurological therapies for individuals afflicted with various neurological diseases. The company developed a prescription inhalation powder to treat Parkinson's disease, began clinical trials in 2015, and received US Food and Drug Administration (FDA) approval to begin manufacturing this new medication. Manufacture of this new medication prompted the need for facility expansion.

The biopharmaceutical manufacturing equipment utilized by Civitas at its Chelsea facility can be used to produce other respiratory medications. Due to the Covid-19 pandemic, Civitas was approached by a pharmaceutical company requesting assistance in the production of a respiratory medication that can be used in the treatment of Covid-19 infected patients.

Compliance History:

During an inspection on December 11, 2019, MassDEP determined that Civitas had commenced construction of manufacturing equipment prior to submitting the appropriate air quality plan application and did not obtain a plan approval (Permit) from MassDEP for the construction/installation of certain equipment at its Chelsea facility. MassDEP initiated an enforcement action to address this violation.

On September 2, 2020, MassDEP executed an Administrative Consent Order with Penalty ("the Order") with Civitas pertaining to hazardous waste and air quality noncompliance issues, including the construction/installation of equipment without obtaining the required MassDEP approvals.

Compliance Requirements:

The Order required Civitas to submit a permit application for the new manufacturing process and the expansion of activities at the facility. On October 1, 2020, Civitas submitted a non-major Comprehensive Plan Application (nmCPA or Application) for its facility expansion project.

To expedite the review of Civitas' installation and operation of the critical manufacturing equipment and allow the manufacture of Covid-19 medication, MassDEP established the Best Available Control Technology (BACT) emission limits for the new manufacturing equipment

and for the entire facility. Civitas agreed to MassDEP's technology determination and emission limits, which are required by the Order to be incorporated into the recently submitted permit Application.

The Order allows Civitas to resume construction and begin operation of the manufacturing equipment prior to receiving the Permit, which will allow Civitas to manufacture the necessary respiratory medication urgently needed by Covid-19 patients. The operation of the manufacturing equipment is subject to the agreed upon BACT determination and emission limits.

The MassDEP enforcement action and resulting Order with Civitas established very stringent requirements for process emissions and BACT emission limits and is not subject to change as a result of public review and comment. The nature of enforcement actions typically results in more stringent emission limits and requirements, as is the case for Civitas. If not for the enforcement action resulting in stringent BACT emission limits, Civitas could have submitted its permit application requesting higher emission limits for its Chelsea facility.

The BACT emission limits is the only permit term not subject to public comment in the proposed permit for Civitas. Other requirements contained within the proposed permit may be changed, modified or deleted, if appropriate, based upon comments received during the public review period.

Current and Proposed Operations:

Civitas currently operates two (2) spray dryers that produce its powdered respiratory product for clinical trial use. The expansion project proposes the installation of an additional spray dryer (Spray Dryer 7) with an associated increase in volatile organic compound (VOC) emissions, specifically alcohol (ethanol) emissions. Other Civitas equipment and activities at the Chelsea facility include a boiler, an emergency generator (for power failures), surface disinfection, and an alcohol/ethanol storage tank. The proposed permitting action includes the addition of new equipment, Spray Dryer 7 and the establishment of facility-wide emission limit (or cap) for all the existing and proposed equipment.

Civitas' emissions in Chelsea:

Civitas uses alcohol, specifically ethanol, as a solvent in its biopharmaceutical manufacturing process. Ethanol is also called ethyl alcohol, grain alcohol, drinking alcohol or spirits. Ethanol is also released/emitted as a by-product during the fermentation process of yeast. Industrial bakeries in the Commonwealth and elsewhere release/emit ethanol during the activation of yeast in bread production.

MassDEP has imposed the following emission restrictions representing BACT for the Civitas Chelsea facility:

BEST AVAILABLE CONTROL TECHNOLOGY (BACT) EMISSION LIMITS CIVITAS THERAPEUTICS, INC.	
Emission Unit Name	VOC tons per 12 month rolling period
Spray Dryer 1	1.6
Spray Dryer 4 and Spray Dryer 7 (new)	9.4*
Quality Assurance/Quality Control Labs	2.9
Surface Disinfection Activities	1.9
Clean-in-Place	0.1
Total Potential Facility-Wide Process VOC Emissions	15.9

*approximately 7 tons of VOC (ethanol) emissions are associated with Spray Dryer 7

Historical VOC emissions from Civitas's biopharmaceutical activities have fluctuated over the years since the facility has operated primarily as a research and development (R&D) institution. VOC emissions from the Civitas Chelsea site have been calculated to be between 2.6 and 4.9 tons per year, as ethanol.

Public Involvement and Impact of this Activity:

MassDEP will be reviewing the Permit Application from Civitas and will consider public input in that process. Although the facility's expansion will result in more emissions of ethanol, as a result of the agency's enforcement action, Civitas has agreed to the most stringent emission limits, and has further agreed to a total facility emission cap, which would not otherwise have been required.

Any questions or comments pertaining to the Civitas plan application should be directed to Edward J. Braczyk, Permit Chief, Bureau of Air and Waste at Edward.Braczyk@mass.gov before January 4, 2021.