



Pfizer Inc.
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

July 1, 2021

Ms. Monica Brothers
EGLE, Air Quality Division
Kalamazoo District Office
7953 Adobe Road
Kalamazoo, MI 49009



Subject: Response to June 15, 2021 Violation Notice
Pharmacia & Upjohn Company LLC, a subsidiary of Pfizer Inc. (Pfizer Kalamazoo)
Renewable Operating Permit MI-ROP-B3610-2014(h)

Dear Ms. Brothers:

On May 27, 2021, Pfizer Kalamazoo notified EGLE AQD that we inadvertently installed two new process tanks without a Permit to Install (PTI) as required by R 336.1201 (Rule 201) and were preparing the PTI application for submittal. These two new tanks are intended to contain acetone and do not qualify for any exemptions from the requirement to obtain a PTI prior to installation. Pfizer Kalamazoo received a Violation Notice (VN) from AQD on June 15, 2021, related to this issue. The VN requires a written response from Pfizer Kalamazoo to AQD by July 6, 2021, that includes the following information:

1. *Dates the violation occurred* – the two tanks were installed in December 2019. We do not have a record of the specific date we initiated installation. The two tanks have never been placed into service and will remain locked out of service until EGLE issues the PTI.
2. *An explanation of the causes* – the two tanks are part of a larger capital project and were not identified during the project's air permit review. The capital project was evaluated by air compliance specialists, who reviewed the project's equipment list, identified one new rotoclone as needing a PTI, and determined the other equipment was exempt. The exemptions were documented internally and the PTI application for the rotoclone was submitted and approved as PTI #26-18.¹ However, the two tanks were not identified during the project scope review and therefore were never evaluated for the need to obtain a PTI.

¹ PTI 16-19A, referenced in the VN, is not associated with this capital project.

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The air compliance specialists and the project manager believed that all equipment was accounted for and evaluated. The project proceeded with equipment installations.

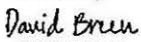
3. *Duration of the violation* – approximately 18 months from the date installed until the PTI application was submitted on June 3, 2021.
4. *Whether the violation is ongoing* – the two tanks were installed in December 2019 and the PTI application was submitted on June 3, 2021; the tanks have never been placed into service and will remain locked out of service until EGLE issues the PTI.
5. *A summary of the actions that have been taken and are proposed to be taken to correct the violation and the dates by which these actions will take place.* In anticipation of project start-up, Pfizer Kalamazoo conducted a record review, which revealed the installation of two tanks subject to Rule 201. Upon discovery of the completed installation of the two new tanks in May 2021 and prior to the tanks being placed into service, the tanks were locked out and will remain locked out from use until EGLE issues the PTI. The PTI application was submitted to EGLE on June 3, 2021. Pfizer Kalamazoo requested a quick turn-around on the PTI review to avoid missing critical plant trial commitments using the new equipment train. To meet these plant trial commitments, Pfizer Kalamazoo would need the PTI for the two tanks by mid-July 2021.
6. *Steps that are being taken to prevent a reoccurrence* – Pfizer Kalamazoo has developed several actions designed to prevent a reoccurrence:
 - a. Air Compliance Program Manual update – the workflow for capital project reviews used by air compliance specialists was updated to ensure all parties have a thorough understanding of every piece of equipment involved in the project and ensure that all parties are working from the same list(s) of equipment. The project will provide a comprehensive equipment list and/or process flow diagram to the air compliance specialist to conduct the permit review. The air compliance specialists will then discuss with the project manager and project engineer all equipment in project scope. The air compliance specialist will complete the review and then communicate to the project team whether each piece of equipment requires a PTI or can be exempt from requirements to obtain a PTI.
 - b. Permit to Install Training for Project Managers – the training uses key information from the EGLE AQD website related to the fundamentals of the PTI program including the core prohibition against installing or constructing new equipment without a PTI. The training also includes a knowledge assessment to verify that the learner understands the critical elements. All project managers will receive this training in July 2021. The training will be added to their learning curricula and required annually as refresher training. New project managers will be trained within 90 days of beginning their new role.

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Should you have any questions, please feel free to contact Steve Maynard at 269.833.9040, or Tim Swainston at 269.833.0080.

Sincerely,

DocuSigned by:

CB853451C18D425.

David Breen
Site Leader
PGS Kalamazoo Site

Email and FedEx # 7740 8884 4397

cc/att: Ms. Jenine Camilleri, Enforcement Unit Supervisor, EGLE AQD, 525 West Allegan Street, Lansing, MI 48913 (Email and FedEx # 7740 8916 1732)