



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

Pfizer Global Supply

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Via email [brothersm@michigan.gov] and FedEx # 7725 0765 4551

June 29, 2023

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

Subject: Response to June 14, 2023, Violation Notice
Pharmacia & Upjohn Company LLC, a subsidiary of Pfizer Inc. (Pfizer
Kalamazoo)
Renewable Operating Permit MI-ROP-B3610-2021(a)

Dear Ms. Brothers:

On June 14, 2023, Pfizer Kalamazoo notified the Michigan Department of Environment, Great Lakes and Energy (EGLE) Air Quality Division (AQD) that Pfizer Kalamazoo inadvertently operated Building 91 (B91) Commercial Product Laboratory (CPL) and B91 East Pack Out Room without a Permit to Install (PTI) as required by R 336.1201 (Rule 201). Pfizer Kalamazoo received a Violation Notice (VN) from EGLE AQD on June 15, 2023, related to these issues. The VN requires a written response from Pfizer Kalamazoo to EGLE AQD by July 6, 2023, that includes the information below. The VN requests are italicized followed by our responses in plain text.

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1. *Dates the violation occurred*

a. B91 CPL

- Approximately 2011 to 2023. B91 CPL is used for small scale production of materials for sale. Stacks EX-67, EX-68, EX-69 and EX-70 were all part of CPL and part of the ROP until they were requested to be removed on April 2, 2013, as a part of the ROP renewal application as the equipment was listed as removed from service. On October 25, 2010, site environmental team approval was given for the hoods and fans of the laboratories in B91 to move to a single discharge point which is not required to be part of the current ROP. The as-built drawings of the new strobic fans are dated December 2011.

b. B91 East Pack Out Room

- Approximately 1996 to 2023. The drawings for the room were issued for construction on April 12, 1996. Emissions from the B91 East Pack Out Room have been accounted for in the B91 emission unit recordkeeping, reported annually in MAERS, and controlled by a particulate control device since the room began operation.

2. *An explanation of the causes*

a. B91 CPL

- Our investigation to date indicates that the B91 laboratory hoods and exhaust stacks were replaced as part of a larger project affecting all of the laboratories in B91 around 2011. There is no express mention that one of the impacted laboratories is used for CPL (also known as Lab 294). As noted above, B91 CPL is used for small scale production of materials for sale, and therefore not eligible for the general lab exemption. The Pfizer Kalamazoo environmental team tasked with reviewing the project for environmental permitting impacts may not have appreciated that one of the subject laboratories is the CPL, which is managed differently from the other laboratories.

b. B91 East Pack Out Room

- Based on our investigation to date, we have been unable to locate any documentation of a request for review by the Pfizer Kalamazoo environmental team, which is one of the required processes for any onsite construction projects. The pack out room, particulate control devices and fan were installed after the original permit for B91 was issued in 1996. However, emissions from the B91 East Pack Out Room have been accounted for in the B91 emission unit recordkeeping, reported annually in MAERS, and controlled by a particulate control device since the room began operation.

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3. *Duration of the violation*

a. B91 CPL

- Approximately 12 years

b. B91 East Pack Out Room

- Approximately 27 years; however, emissions from the B91 East Pack Out Room have been accounted for in the B91 emission unit recordkeeping, reported annually in MAERS, and controlled by a particulate control device since the room began operation.

4. *Whether the violation is ongoing*

a. B91 CPL

- The violation is no longer occurring. A PTI application was submitted for B91 CPL on June 15, 2023. B91 CPL has discontinued all solids handling activities until EGLE issues the PTI.

b. B91 East Pack Out Room

- The violation is no longer occurring. A PTI application for B91 East Pack Out Room is being drafted and will be submitted once complete. No production will be allowed in B91 East Pack Out Room until the PTI has been issued final.

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.*

a. B91 CPL

- There are currently no solids handling activities running in the laboratory. A PTI application was submitted on June 15, 2023, for review and approval by EGLE AQD.

b. B91 East Pack Out Room

- The pack out room has been removed from service and no production is allowed until a PTI has been issued final by EGLE AQD.

6. *Steps that are being taken to prevent a reoccurrence* – Pfizer Kalamazoo has developed several actions designed to prevent a reoccurrence:

a. Since 2021, the site has implemented several actions that will prevent a recurrence. Those actions were more comprehensive meetings with project managers for capital projects, more detailed work processes for change control reviews, and detailed training to project managers related to air permitting requirements including annual refresher training.

b. Beginning in 2023, when a change is proposed, the Pfizer Kalamazoo environmental team reviews HVAC drawings, walks down solid and volatile handling and charging areas, and field verifies the drops to the area are connected to a permitted particulate control device and stack.

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Pfizer Kalamazoo remains committed to leading in environmental stewardship and full compliance with all regulations. Should you have any questions, please feel free to contact Steve Maynard at 269.833.9040, or Tim Swainston at 269.833.0080.

Sincerely,



Jill June
Site Leader – Kalamazoo
PGS Global Sterile Injectables

cc/att: Ms. Jenine Camilleri, Enforcement Unit Supervisor, EGLE AQD, 525 West Allegan Street, Lansing, MI 48913 (Email [camillerj@michigan.gov] and FedEx # 7725 0774 0661)