DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: On-site Inspection

B232964919

FACILITY: Par Sterile Products LLC		**SRN / ID:** B2329
LOCATION: 870 PARKDALE RD, ROCHESTER		**DISTRICT:** Warren
CITY: ROCHESTER		**COUNTY:** OAKLAND
CONTACT: Annette Sommers , Associate Director EH&S, Workforce Dev.		**ACTIVITY DATE:** 09/16/2022
STAFF: Adam Bognar	**COMPLIANCE STATUS:** Non Compliance	**SOURCE CLASS:** SM OPT OUT
SUBJECT: Scheduled Inspection		
RESOLVED COMPLAINTS:		

On Friday, September 16, 2022, Michigan Department of Environment, Great Lakes, and Energy-Air Quality Division (EGLE-AQD) staff, I, Adam Bognar, conducted a scheduled inspection of Par Sterile Products LLC (the "Facility" or "Par Pharmaceuticals") located at 870 Parkdale Road, Rochester, MI. The purpose of this inspection was to determine the facility's compliance status with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control of Natural Resources and Environmental Protection Act, 1994 Public Act 451; Michigan Department of Environment, Great Lakes, and Energy -Air Quality Division (EGLE-AQD) rules; 40 CFR Part 60 Subpart JJJJ & IIII – Standards of Performance for Stationary Spark Ignition & Compression Ignition Internal Combustion Engines; and Permit to Install No. 73-21.

I arrived at the facility at around 10 am. I met with Annette Sommers, Associate Director of Environmental Health and Safety. I identified myself and stated the purpose of the inspection. Annette gave me a tour of the facility. We did not review records while on-site. Annette provided all of the requested records to me prior to this inspection on September 9, 2022. I performed the detailed record review in my office after the data was emailed to me.

These records are available on the AQD shared drive at the following address: S:\Air Quality Division\STAFF\Bognar, Adam\Inspection Documents\Par Sterile Products 2022

Par Sterile Products develops, manufacturers, and markets a broad portfolio of branded and generic aseptic injectable pharmaceuticals. The facility receives the active pharmaceutical components from other businesses and packages them into a sterile injectable form. No active pharmaceuticals are manufactured here – active pharmaceuticals are mixed with other components and repackaged.

The facility produces products such as adrenalin injections, delestrogen injections, ketalar injections, and dozens of other injectable products.

There are around 457 employees that operate this facility 7 days a week over 3 shifts.

Previously, the facility operated under an Renewable Operating Permit (ROP) as a Title V major source. Several emission units that were covered under the ROP were either uninstalled or rendered inoperable, allowing the source to opt-out of the ROP program and operate as a synthetic minor source for HAPs. Par Sterile Products received permit No. 73-21 on September 30, 2021.

PTI No. 73-21

FGEMERGENS

Section I – Special Conditon 1,2,3: Specifies emission limits for FGEMERGENS. Non methane hydrocarbons and NOx emissions are limited to 6.4 g/kW-hr, Carbon Monoxide emissions are limited to 3.5 g/kW-hr, and Particulate Matter emissions are limited to 0.20 g/kW-hr. Par Sterile Products submitted USEPA Certificate of Conformity documents showing that the Cummins and Kohler engines are USEPA certified engines with respect to 40 CFR Part 60. Since these engines are EPA certified, compliance with these emission limits is demonstrated by operating the engines according to the manufacturer's emission-related written instructions. Par Pharmaceuticals provided me with records of maintenance activities performed on the engines. The Kohler engine was serviced on October 15, 2021 and the Cummins engine was serviced on August 26, 2022. Based on my inspection and the records I reviewed, these engines are operated according to the manufacturer's emission-related instructions.

Section II – Special Condition 1: Limits the type of diesel fuel used in FGMERGENS. The diesel fuel can have a maximum sulfur content of 15 ppm (0.0015%) and a Cetane index of 40 or a maximum aromatic content of 35 volume percent.

Annette provided me with the safety data sheet for the diesel fuel. "Marathon Petroleum No. 2 Ultra Low Sulfur Diesel is used in both engines. The data sheet indicates that sulfur content is less than 15 ppm. The total aromatic content in this fuel is up to 5%. This fuel complies with these limits based on the safety data sheet I reviewed.

Section III – Special Condition 1: States that the permittee shall not operate each engine in FGEMERGENS for more than 500 hours per year. The facility has not operated the engines for more than 500 hours per year based on the records I reviewed. Total hours operated for the Kohler 1300kW engine was reported highest during the 12-month period ending in January 2022 at 5.4 hours. Total hours operated for the Cummins 500W engine was reported highest during the 12-month period ending in January 2022 at 10 hours. The records show that neither engine was utilized for emergency use during the periods I reviewed.

Section III – Special Condition 2: States that the permittee shall not operate each engine within FGEMERGENS for more than 100 hours per calendar year for the purpose of necessary maintenance checks and readiness testing. Par Pharmaceuticals is in compliance with this limit based on the records I reviewed.

Section III – Special Condition 3: Allows the engine to operate up to 50 hours per calendar for non-emergency situations, but those 50 hours are counted towards the 100 hours per calendar year provided for maintenance and readiness testing. Par Pharmaceuticals is in compliance with this limit based on the records I reviewed.

Section III – Special Condition 4: States that if the permittee purchased a certified engine, then the permittee shall operate and maintain the engine according to the manufacturer's emission related written instructions. Both engines are USEPA certified for compliance 40 CFR Part 60 and are operated according to the manufacturer's emission related written instructions based on the records I reviewed.

Based on the maintenance records I reviewed, these engines are operated and maintained according the manufacturer's emission related instructions. The maintenance records indicate that a full service was completed on both engines during the period I reviewed (last 12-months).

Section III – Special Condition 5: n/a since Par Pharmaceuticals purchased USEPA certified engines.

Section IV – Special Condition 1: States that the permittee shall equip each engine in FGEMERGENS with a non-resettable hour meter to track operating hours. I verified that both engines are equipped with a non-resettable hour meter. During this inspection, EULABDIESELGEN showed 177.4 total hours and EUDIESELGEN showed 121 total hours.

Section IV – Special Condition 2,3: Limits the maximum power output of EULABDIESELGEN to 755 HP and EUDIESELGEN to 1744 HP as certified by the equipment manufacturer. Based on my observations during this inspection, these engines do not exceed these stated power outputs.

Section V – Special Condition 1 – States that if either engine within FGEMERGENS is not installed, configured, operated, and maintained according to the manufacturer's emission-related written instructions, then the permittee must complete a performance test within 1 year. Based on my review of the most recent maintenance activities, these engines are configured, operated, and maintained properly.

Section VI – Special Condition 1,2,3,4,5: Specifies recordkeeping requirements for FGEMERGENS. Par Pharmaceuticals must keep records of the manufacturer's certification documentation, the fuel sample test data of each diesel delivery, a copy of the manufacturer's emission-related written instructions, and records demonstrating that the engine has been maintained according to those emission-related instructions.

Additionally, Par Pharmaceuticals must maintain records of the total hours of operation of each engine during emergency and non-emergency service. These records are maintained

Section VII – Special Condition 1: Requires the permittee to submit a notification specifying whether each engine in FGEMERGENS will be operated in a certified or non-certified manner within 30 days following the initial startup of the engine or after switching the manner of operation. I did not verify that this notification was submitted. The Kohler engine was installed in 2018 and the Cummins engine was installed in 2013.

Section IX – Special Condition 1: States that the permittee shall comply with the provisions of the Standards of Performance for New Stationary Sources as specified in 40 CFR Part 60, Subparts A and IIII. Based on the maintenance records I reviewed, the engines comply with these standards.

Section IX – Special Condition 2: States that the permittee shall comply with the provisions of the National Emission Standards for Hazardous Air Pollutants as specified in 40 CFR Part 63, Subparts A and ZZZZ. Based on the maintenance records I reviewed, the engines comply with these standards.

FG-IPA-USE

This flexible group includes all IPA use throughout the facility for cleaning and disinfecting process equipment and removing labels from containers.

Section I – Special Condition 1: Limits emissions of isopropyl alcohol (IPA) to 24 tons per year. Par Pharmaceuticals meets this emission limit based on the records I reviewed. IPA emissions are reported at 9.63 tons during each 12-month rolling period. This is because Par Pharmaceuticals orders the same amount of IPA wipes every month. Annette assumes that all the IPA wipes purchased are used each month.

Section VI – Special Condition 1,2: Specifies recordkeeping requirements for FG-IPA-USE. Par Pharmaceuticals must keep records of the gallons and pounds of IPA used per month as well as IPA emissions on a monthly and 12-month rolling time period. Par Pharmaceuticals provided me with these records.

FGFACILITY

Section I – Special Condition 1,2: Limits emissions of each individual HAP to 8.9 tons and aggregate total HAPs to 22.4 tons. Aggregate HAPs were reported highest during the 12-month period ending in August 2022 at 0.934 tons.

Section VI – Special Condition 1,2: Specifies recordkeeping requirements for FGFACILTIY. Par Pharmaceuticals must maintain records of individual and aggregate HAP emissions on a 12-month rolling basis. I verified that these records are maintained.

Natural gas emergency generator

This is a 770 HP generator manufactured by Cummins/Onan. The generator was onboarded in April 2020 (gas hooked up and preventative maintenance starts). Annette provided me with preventative maintenance records showing that the engine was serviced by Cummins on April 14, 2021. Annette was not able to provide me with a document certifying EPA compliance with 40 CFR Part 60, Subpart JJJJ – Standards of Performance for Stationary Spark Ignition Internal Combustion Engines (NSPS JJJJ). Annette checked the name plate on the generator and reached out to the generator manufacturer and was not able to obtain this certification.

Since the generator is not certified for compliance with NSPS JJJJ, Par Sterile Products must conduct a performance test on the generator in accordance with 40 CFR 60.4244 to demonstrate compliance with Table 1 of NSPS JJJJ. The engine is larger than 500 HP so this testing will be required every 8,760 hours or 3 years, whichever comes first, to demonstrate compliance. 40 CFR Part 60 Subpart A (60.8(a)) states that this testing must be conducted within 180 days of initial startup. This test was never conducted.

This is a violation of 40 CFR 60.4243(b)(2)(ii) and 40 CFR 60.8(a). A violation notice will be sent to Par Sterile Products for operating this generator without conducting the required initial performance test.

Another building was installed next to this generator around the same time. Annette stated that this building contains cooling towers. I did not enter this building during my inspection.

Rule 290

The manufacturing activities at this facility are exempt from Rule 201 requirements pursuant to Rule 290 based on the records I reviewed. Par Pharmaceuticals provided a document showing emissions of individual toxic air contaminants from the manufacturing process on a monthly and 12 -month rolling basis. 6 individual toxic air contaminants are identified – Hydrochloric acid, phenol, hexane, formaldehyde, propylene, and manganese.

The records I reviewed show that total uncontrolled emissions of air contaminants from manufacturing activities are less than 1,000 lbs/month. The table below shows the highest monthly emissions for each of these compounds. Even if all the highest monthly emissions were added together, total monthly emissions would be 160 lbs from this process. Both formaldehyde and manganese have a 20 lb/month emission limit based on their ITSL/IRSL.

Compound	Highest Individual Month Emissions (lbs)
HCL	1.1
Phenol	1.66
Hexane	140
Formaldehyde	9.34
Propylene	8.56
Manganese	0.02

Compliance Determination

Par Sterile Products failed to conduct an initial performance test on their 770 HP natural gas fired spark ignition internal combustion engine. This is a violation of 40 CFR 60.4243(b)(2)(ii). A violation notice will be sent to Par Sterile Products for operating this generator without conducting the required initial performance test.

Par Sterile Products appears to be operating in compliance with all other requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); Michigan Department of Environment, Great Lakes, and Energy-Air Quality Division (EGLE-AQD) Administrative Rules; 40 CFR Part 60 Subpart JJJJ & IIII – Standards of Performance for Stationary Spark Ignition & Compression Ignition Internal Combustion Engines; and Permit to Install No. 73-21.

NAME Adam Bognar DATE 10/5/2022 SUPERVISOR K. Kelly