Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

Via FedEx # 7794 5047 4332 and Email [EGLE-ROP@michigan.gov]

October 28, 2024

EGLE - Air Quality Division
Grand Rapids District Office
350 Ottawa Ave NW
Unit 10
Grand Rapids, MI 49503

RE: Minor Modification – Rule 216 (2) – Permit to Install No. 118-24

Dear EGLE ROP Team:

Attached, please find the C-001 form, M-001 form, AI-001 form and marked-up Renewable Operating Permit (ROP) required to complete the minor modification to incorporate Permit to Install (PTI) No. 118-24 into the ROP No. MI-ROP-B3610-2021a. The affected emission unit is in Section 3 of the ROP.

If you need additional information or have any questions or concerns, please contact Tim Swainston at 269.833.0080 or Timothy.Swainston@pfizer.com.

Sincerely,

Jill June
Site Leader – Kalamazoo

PGS
Global Sterile Injectables

cc/att: Michael Cox – Email Only [coxm9@michigan.gov]

EGLE Michigan Department of Environment, Great Lakes, and Energy - Air Quality Division

RENEWABLE OPERATING PERMIT APPLICATION
C-001: CERTIFICATION

This information is required by Article II, Chapter 1, part 55 (Air Pollution Control) of P.A. 451 of 1994, as amended, and the Federal Clean Air Act of 1990. Failure to provide this information may result in civil and/or criminal penalties. Please type or print clearly.

This form is completed and included as part of Renewable Operating Permit (ROP) initial and renewal applications, notifications of change, amendments, modifications, and additional information.

Form Type **C-001**	SRN B3610

Stationary Source Name Pharmacia & Upjohn LLC, a subsidiary of Pfizer Inc.	
City Kalamazoo	County Kalamazoo

SUBMITTAL CERTIFICATION INFORMATION

1. Type of Submittal *Check only one box.*

☐ Initial Application (Rule 210) ☒ Notification / Administrative Amendment / Modification (Rules 215/216)

☐ Renewal (Rule 210) ☐ Other, describe on AI-001

2. If this ROP has more than one Section, list the Section(s) that this Certification applies to 3

3. Submittal Media ☒ E-mail ☐ FTP ☐ Disk ☒ Paper

4. Operator's Additional Information ID - Create an Additional Information (AI) ID that is used to provide supplemental information on AI-001 regarding a submittal.

AI -001

CONTACT INFORMATION

Contact Name Timothy Swainston	Title Senior EHS Specialist - Environmental
Phone number 269-833-0080	E-mail address timothy.swainston@pfizer.com

This form must be signed and dated by a Responsible Official.

Responsible Official Name Jill June			Title Site Leader	
Mailing address 7000 Portage Rd.				
City Kalamazoo	State MI	ZIP Code 49001	County Kalamazoo	Country United States

As a Responsible Official, I certify that, based on information and belief formed after reasonable inquiry, the statements and information in this submittal are true, accurate and complete.

J June — Signature of Responsible Official

10/28/2024 — Date

App No. 202400291

EGLE

Michigan Department of Environment, Great Lakes, and Energy
Air Quality Division

RENEWABLE OPERATING PERMIT
M-001: RULE 215 CHANGE NOTIFICATION
RULE 216 AMENDMENT/MODIFICATION APPLICATION

This information is required by Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended, and the Federal Clean Air Act of 1990. Failure to obtain a permit required by Part 55 may result in penalties and/or imprisonment.

1. SRN B3610	2. ROP Number MI-ROP-B3610-2021a	3. County Kalamazoo
4. Stationary Source Name	Pharmacia & Upjohn LLC, a subsidiary of Pfizer Inc.	
5. Location Address	7000 Portage Rd.	6. City Kalamazoo

7. Submittal Type - *The submittal must meet the criteria for the box checked below. Check only one box. Attach a mark-up of the affected ROP pages for applications for Rule 216 changes.*

- ☐ **Rule 215(1) Notification of change**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 215(2) Notification of change**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 215(3) Notification of change**. *Complete Items 8 – 11 and 14*
- ☐ **Rule 215(5) Notification of change**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 216(1)(a)(i)-(iv) Administrative Amendment**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 216(1)(a)(v) Administrative Amendment**. *Complete Items 8 – 14. Results of testing, monitoring & recordkeeping must be submitted. See detailed instructions.*
- ☒ **Rule 216(2) Minor Modification**. *Complete Items 8 – 12 and 14*
- ☐ **Rule 216(3) Significant Modification**. *Complete Items 8 – 12 and 14, and provide any additional information needed on ROP application forms. See detailed instructions.*
- ☐ **Rule 216(4) State-Only Modification**. *Complete Items 8 – 12 and 14*

8. Effective date of the change. (MM/DD/YYYY) *See detailed instructions.* 10/29/2024	9. Change in emissions? ☐ Yes ☒ No

10. Description of Change - *Describe any changes or additions to the ROP, including any changes in emissions and/or pollutants that will occur. If additional space is needed, complete an Additional Information form (AI-001).*

Incorporate updated requirement for permit to install (PTI) 118-24. Allow for new condition in issue PTI to be used.

11. New Source Review Permit(s) to Install (PTI) associated with this application? ☒ Yes ☐ No

If Yes, enter the PTI Number(s) 118-24 ____-____ ____-____ ____-____ ____-____

12. Compliance Status - *A narrative compliance plan, including a schedule for compliance, must be submitted using an AI-001 if any of the following are checked No.*

a. Is the change identified above in compliance with the associated applicable requirement(s)? ☒ Yes ☐ No

b. Will the change identified above continue to be in compliance with the associated applicable requirement(s)? ☒ Yes ☐ No

c. If the change includes a future applicable requirement(s), will timely compliance be achieved? ☒ Yes ☐ No

13. Operator's Additional Information ID - *Create an Additional Information (AI) ID for the associated AI-001 form used to provide supplemental information.* **AI -001**

14. Contact Name	Telephone No.	E-mail Address
Timothy Swainston	269-833-0080	timothy.swainston@pfizer.com

15. This submittal also updates the ROP renewal application submitted on ____/____/____ ☐ Yes ☒ N/A
(If yes, a mark-up of the affected pages of the ROP must be attached.)

NOTE: A CERTIFICATION FORM (C-001) SIGNED BY A RESPONSIBLE OFFICIAL MUST ACCOMPANY ALL SUBMITTALS

Michigan Department of Environment, Great Lakes, and Energy - Air Quality Division

EGLE

RENEWABLE OPERATING PERMIT APPLICATION
AI-001: ADDITIONAL INFORMATION

This information is required by Article II, Chapter 1, Part 55 (Air Pollution Control) of P.A. 451 of 1994, as amended, and the Federal Clean Air Act of 1990. Failure to obtain a permit required by Part 55 may result in penalties and/or imprisonment. Please type or print clearly. Refer to instructions for additional information to complete this form.

SRN: B3610	Section Number (if applicable): 3

1. Additional Information ID
AI-001

Additional Information

2. Is This Information Confidential? ☐ Yes ☒ No

Attached are the marked-up pages of ROP No. MI-ROP-B3610-2021a.

Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a
Expiration Date: October 18, 2026
PTI No: MI-PTI-B3610-2021a

Emission Unit ID	Emission Unit Description (Including Process Equipment & Control Device(s))	Installation Date/ Modification Date	Flexible Group ID
EUCR138-S3	All equipment in or around Building 38 located in (Active Pharmaceutical Ingredients) API Region I. Particulate emissions are controlled by a number of pollution control equipment, including a new W-Rotoclone (038ROTO0214-1).	01-01-1946/ 11-30-2010/ 09-08-2020	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1127-S3	All equipment in or around Building 127 located in API Region I.	01-01-1964/ 11-30-2010	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1155-S3	All equipment in or around Building 155 located in API Region I.	01-01-1966/ 12-11-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1166-S3	All equipment in or around Building 166 located in API Region I.	01-01-1966/ 12-11-1995	FGCRALLPART-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1195-S3	All equipment in or around Building 195 located in API Region I. (PTI No. 81-15)	01-01-1971/ 12-11-1995/ 06-02-2015	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR244-S3	All equipment in or around Building 44 located in API Region II.	01-01-1938 06-01-1996	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR2149-S3	All equipment in or around Building 149 located in API Region II.	01-01-1965/ 06-01-1996	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR373-S3	All equipment in or around Building 73 located in API Region III. Permit to Install No. 82-16 added Column 10, Tank1830-1, Tank1831-1, and Tank 1832-1 to the emission unit.	01-01-1952/ 06-14-1995 06-28-2016	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR3173-S3	All equipment in or around Building 173, located in KAPI Region III.	01-01-1967/ 06-14-1995/ 08-13-19 07-16-2021	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR3207-S3	All equipment in or around Building 207 located in API Region III.	01-01-1975/ 06-14-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR3225-S3	All equipment in or around Building 225. Located in API Region III.	01-01-1976/ 06-14-1995/ 03-15-2016/ 02-07-2019/ 09-13-2021/ 01-31-2022/ 03-17-2023/ 10-29-2024	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
12. VOC (total)	3.91 tpy[2]	12-month rolling time period as determined at the end of each calendar month	~~Unconnected silica slurry exhaust hood~~High-performance liquid chromatography column loading process exhausted through SCRB1006	SC VI.6	**R 336.1702(a)**

Emission Limits for PM, PM10, and PM2.5							
	PM, PM10, and PM2.5			PM only			
Exhaust ID	**Lbs Per Hour By Size Category[+]**			**Lbs Particulate Per 1000 Lbs Of Dry Exhaust Gas**			**Maximum Gas Flow Rate (dscfm)**
	A	**B**	**C**	**A**	**B**	**C**	
13. EF1C1HB1	0.14	0.1	0.06	0.01	0.01	0.006	2,400
14. SCRB1006	0.82	0.41	0.21	0.01	0.01	0.006	24,000
15. SCRB1007	0.41	0.21	0.1	0.01	0.01	0.006	12,000
16. EX-27	0.33	0.24	0.14	0.01	0.01	0.006	5,500
17. EX-30	0.12	0.09	0.05	0.01	0.01	0.006	2,000
18. EX-34	0.34	0.24	0.15	0.01	0.01	0.006	5,700

[+]See Appendix 10-S3 for approved procedures for determination of the particle size category.

II. MATERIAL LIMITS

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Material produced in PM-emitting activities	115 lots/month[1]	Calendar month	EUCR3225-S3	SC VI.5	**R 336.1225, R 336.1227(2)**
2. Lots of product produced in VOC processes.	30 lots/month[2]	Calendar month	EUCR3225-S3	SC VI.7	**R 336.1225, R 336.1227(2), R 336.1702(a)**
3. Material produced in 1MAV-emitting activities	90 kg/lot[1]	Calendar month	EUCR3225-S3	SC VI.8	R 336.1226(a)
4. Material produced in 2MAV-emitting activities	90 kg/lot[1]	Calendar month	EUCR3225-S3	SC VI.9	R 336.1226(a)

III. PROCESS/OPERATIONAL RESTRICTIONS

1. Except for the T-K271 unconnected bypass vent and the high-performance liquid chromatography column loading process exhausted through SCRB1006, t~~T~~he permittee shall not operate equipment located in EUCR3225-S3 in vacuum service while processing a VOC unless the vacuum pump is connected to the thermal oxidizer control and the thermal oxidizer control is installed, maintained, and operated in a satisfactory manner.[2] **(R 336.1224, R 336.1225, R 336.1702(a), R 336.1910)**

2. The permittee shall capture all waste materials from the solvent cleaning of the solids drum charging glove boxes and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable

IV. DESIGN/EQUIPMENT PARAMETER(S)

NA

V. TESTING/SAMPLING

Records shall be maintained on file for a period of five years. **(R 336.1213(3)(b)(ii))**

NA

VI. MONITORING/RECORDKEEPING

Records shall be maintained on file for a period of five years. **(R 336.1213(3)(b)(ii))**

1. The permittee shall complete all required records in a format acceptable to the AQD District Supervisor and make them available by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition.[2] **(R 336.1225, R 336.1702(a), R 336.1331(c), R 336.1910)**

2. The permittee shall calculate and record the actual PM, PM10, and PM2.5 emission rates on a monthly basis using a method similar to that described in Appendix 4-S3.[2] **(R 336.1225, R 336.1227(2), R 336.1331(c))**

3. The permittee shall calculate the actual VOC emissions from ~~each process for unconnected VOC equipment while emitting from the unconnected bypass vent of~~the T-K271 unconnected bypass vent for each calendar month using the method detailed in Appendix 4-S3.[2] **(R 336.1702(a))**

4. The permittee shall conduct and record the results of a visible emission observation (described in Appendix 3-S3) of the particulate control device exhausts once per calendar month during a period when the particulate control devices are being operated.[2] **(R 336.1331)**

5. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in PM-emitting activities in EUCR3225-S3 on a calendar month basis.[1] **(R 336.1225, R 336.1227(2))**

6. The permittee shall calculate the actual VOC emissions from the ~~silica slurry~~high-performance liquid chromatography column loading process exhausted through SCRB1006 exhaust hood for each calendar month and 12-month rolling time period, as determined at the end of each calendar month, in a format acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and shall make them available to the department upon request.[2] **(R 336.1702(a))**

7. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in VOC-emitting activities in EUCR3225-S3 on a calendar month basis.[1] **(R 336.1225, R 336.1227(2))**

8. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in kg/lot, produced in 1MAV-emitting activities in EUCR3225-S3 on a calendar month basis.[1] **(R 336.1226(a))**

9. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in kg/lot, produced in 2MAV-emitting activities in EUCR3225-S3 on a calendar month basis.[1] **(R 336.1226(a))**

~~7.~~

See Appendix 4-S3

VII. REPORTING

1. ~~1.~~ Within 30 days after completion of the installation, construction, reconstruction, relocation, or modification authorized by this Permit to Install, the permittee or the authorized agent pursuant to Rule 204, shall notify the AQD District Supervisor, in writing, of the completion of the activity. Completion of the installation, construction, reconstruction, relocation, or modification is considered to occur not later than commencement of trial operation of high-performance liquid chromatography for the PGE2 process in EUCR3225-S3. **(R 336.1201(7)(a))**

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2. Prompt reporting of deviations pursuant to General Conditions 21 and 22 of Part A. **(R 336.1213(3)(c)(ii))**

32. Semiannual reporting of monitoring and deviations pursuant to General Condition 23 of Part A. The report shall be postmarked or received by the appropriate AQD District Office by March 15 for reporting period July 1 to December 31 and September 15 for reporting period January 1 to June 30. **(R 336.1213(3)(c)(i))**

43. Annual certification of compliance pursuant to General Conditions 19 and 20 of Part A. The report shall be postmarked or received by the appropriate AQD District Office by March 15 for the previous calendar year. **(R 336.1213(4)(c))**

See Appendix 8-S3

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VIII. STACK/VENT RESTRICTIONS

The exhaust gases from the stacks listed in the table below shall be discharged unobstructed vertically upwards to the ambient air unless otherwise noted:

Stack & Vent ID	Maximum Exhaust Dimensions (inches)	Minimum Height Above Ground (feet)	Underlying Applicable Requirements
1. SVC225EF1C1HB1	14 [2]	55 [2]	**R 336.1225, 40 CFR 52.21(c) and (d)**
2. SVC225EX27	29 [2]	68 [2]	**R 336.1225, 40 CFR 52.21(c) and (d)**
3. SVC225EX30	17 [2]	54 [2]	**R 336.1225, 40 CFR 52.21(c) and (d)**
4. SVC225EX34	25 [2]	53 [2]	**R 336.1225, 40 CFR 52.21(c) and (d)**
5. SVC225SCRB1006	35 [2]	79 [2]	**R 336.1225, 40 CFR 52.21(c) and (d)**
6. SVC225SCRB1007	25 [2]	80 [2]	**R 336.1225, 40 CFR 52.21(c) and (d)**
7. SVC225TK271	4 [1]	61 [1]	**R 336.1225, 40 CFR 52.21(c) and (d)**

IX. OTHER REQUIREMENT(S)

1. The permittee shall comply with all applicable provisions of the National Emission Standards for Hazardous Air Pollutants, as specified in 40 CFR Part 63, Subpart A and Subpart GGG for Pharmaceuticals Production by the initial compliance date.[2] **(40 CFR Part 63, Subparts A and GGG)**

Footnotes:
[1] This condition is state only enforceable and was established pursuant to Rule 201(1)(b).
[2] This condition is federally enforceable and was established pursuant to Rule 201(1)(a).

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR3225-S3 for the T-K271 unconnected bypass vent.. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION III UNCONNECTED VOC EQUIPMENT PROCESSES			
Process Building	VOC Maximum (lbs/lot)	Actual Number of lots/month	Estimated VOC Emissions (lbs/month)
225	2.5		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR491COM-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION IV UNCONNECTED VOC EQUIPMENT PROCESSES			
Process Building	VOC Maximum (lbs/lot)	Actual Number of lots/month	Estimated VOC Emissions (lbs/month)
91	10		

Appendix 5-S3. Testing Procedures

Specific testing requirement plans, procedures, and averaging times are detailed in the appropriate Source-Wide, Emission Unit and/or Flexible Group Special Conditions. Therefore, this appendix is not applicable.

Appendix 6-S3. Permits to Install

The following table lists any PTIs issued or ROP revision applications received since the effective date of the previously issued ROP No. MI-ROP-B3610-2014. Those ROP revision applications that are being issued concurrently with this ROP renewal are identified by an asterisk (*). Those revision applications not listed with an asterisk were processed prior to this renewal.

Source-Wide PTI No MI-PTI-B3610-2014h is being reissued as Source-Wide PTI No. MI-PTI-B3610-2021a.

Permit to Install Number	ROP Revision Application Number	Description of Equipment or Change	Corresponding Emission Unit(s) or Flexible Group(s)
66-14	201400136/ November 10, 2014	Incorporate PTI No. 66-14. PTI No. 66-14 is for installation of a new tank that will be used to produce steroid intermediate products including hydrocortisone, clindamycin, and hydroxyprednisolone. The new tank will be used for processes that were previously performed on other equipment in the same building, Building 225. No new products will be introduced with the installation of the tank. Neither the production rate nor the emissions rates will increase. No new emission points	EUCR3225-S3