



Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

January 29, 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. 30-21B

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. 30-21B 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,

A handwritten signature in black ink that reads 'Jill June'.

Jill June
Site Leader – Kalamazoo

PGS
Global Sterile Injectables

Email and FedEx # 7746 3981 7830

cc/att: Michael Cox – Email Only



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.

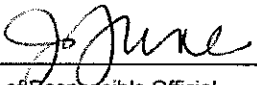
This form is completed and included as part of Renewable Operating Permit (ROP) initial and renewal applications, notifications of change, amendments, modifications, and additional information.

Form Type C-001	SRN B3610
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Stationary Source Name Pharmacia & Upjohn LLC, a subsidiary of Pfizer Inc.	
City Kalamazoo	County Kalamazoo

SUBMITTAL CERTIFICATION INFORMATION	
1. Type of Submittal <i>Check only one box.</i>	
<input type="checkbox"/> Initial Application (Rule 210)	<input checked="" type="checkbox"/> Notification / Administrative Amendment / Modification (Rules 215/216)
<input type="checkbox"/> Renewal (Rule 210)	<input type="checkbox"/> Other, describe on AI-001
2. If this ROP has more than one Section, list the Section(s) that this Certification applies to <u>3</u>	
3. Submittal Media <input checked="" type="checkbox"/> E-mail <input type="checkbox"/> FTP <input type="checkbox"/> Disk <input checked="" type="checkbox"/> 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.				
 Signature of Responsible Official			<u>29 Jan 2024</u> Date	



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
<p>7. Submittal Type - <i>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.</i></p> <p><input type="checkbox"/> Rule 215(1) Notification of change. Complete Items 8 – 10 and 14</p> <p><input type="checkbox"/> Rule 215(2) Notification of change. Complete Items 8 – 10 and 14</p> <p><input type="checkbox"/> Rule 215(3) Notification of change. Complete Items 8 – 11 and 14</p> <p><input type="checkbox"/> Rule 215(5) Notification of change. Complete Items 8 – 10 and 14</p> <p><input type="checkbox"/> Rule 216(1)(a)(i)-(iv) Administrative Amendment. Complete Items 8 – 10 and 14</p> <p><input type="checkbox"/> Rule 216(1)(a)(v) Administrative Amendment. Complete Items 8 – 14. Results of testing, monitoring & recordkeeping must be submitted. See detailed instructions.</p> <p><input checked="" type="checkbox"/> Rule 216(2) Minor Modification. Complete Items 8 – 12 and 14</p> <p><input type="checkbox"/> Rule 216(3) Significant Modification. Complete Items 8 – 12 and 14, and provide any additional information needed on ROP application forms. See detailed instructions.</p> <p><input type="checkbox"/> Rule 216(4) State-Only Modification. Complete Items 8 – 12 and 14</p>		
8. Effective date of the change. (MM/DD/YYYY) <i>See detailed instructions.</i> <u>01/30/2024</u>		9. Change in emissions? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>10. Description of Change - <i>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).</i></p> <p>Incorporate requirements for PTI 30-21B. Allow startup of the SDNF located in B173.</p>		
11. New Source Review Permit(s) to Install (PTI) associated with this application?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, enter the PTI Number(s) <u>30-21B</u> - - - - -		
12. Compliance Status - <i>A narrative compliance plan, including a schedule for compliance, must be submitted using an AI-001 if any of the following are checked No.</i>		
a. Is the change identified above in compliance with the associated applicable requirement(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
b. Will the change identified above continue to be in compliance with the associated applicable requirement(s)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
c. If the change includes a future applicable requirement(s), will timely compliance be achieved?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
13. Operator's Additional Information ID - <i>Create an Additional Information (AI) ID for the associated AI-001 form used to provide supplemental information.</i>		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 ___/___/___		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> N/A
<i>(If yes, a mark-up of the affected pages of the ROP must be attached.)</i>		

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

For Assistance
Contact: 800-662-9278

www.michigan.gov/egle

EQP 5775 (Rev.04-2019)

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



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
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1. Additional Information ID AI-001

Additional Information

2. Is This Information Confidential?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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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-Rotocloner (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 01-30-2024	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	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3

Section 3 – Active Pharmaceutical Ingredients (API)

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

**EUCR3173-S3
 EMISSION UNIT CONDITIONS**

DESCRIPTION

All equipment in or around Building 173, located in KAPI Region III.

Flexible Group ID: FGCRALLPART-S3, FGCRALLTOX-S3, FGCFUG-S3, FGPHARMAMACT-S3

POLLUTION CONTROL EQUIPMENT

W-Rotoclones on EX6, EX25, EX34; Particle Scrubber on SCRB1002; Exhaust Fans on FANS3345, FANS3346; Scrubbers, connected to TOX; Condensers, connected to TOX.

I. EMISSION LIMITS

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. PM	240 lbs ¹	Per month	All process vents combined	SC V.1, SC VI.2	R 336.1225, R 336.1227(2)
2. PM	Limits in the table below: ²	Hourly	EUCR3173-S3	SC V.1	R 336.1225, R 336.1331(c)

Exhaust ID	Lbs Particulate 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	
3. EX-6	0.69	0.17	0.17	0.08	0.02	0.02	2,000
4. EX-25	1.37	0.34	0.34	0.08	0.02	0.02	4,000
5. EX-34	0.93	0.23	0.23	0.08	0.02	0.02	2,700
6. SCRB1002	1.17	0.58	0.29	0.008	0.004	0.002	34,000
7. FANS3345	-	0.29	0.17	-	0.10	0.06	670
8. FANS3346	-	0.29	0.17	-	0.10	0.06	670

II. MATERIAL LIMITS

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Lots of product produced in TSP processes.	150 lots ¹	Per month	EUCR3173-S3	SC VI.2	R 336.1225, R 336.1227(2)

III. PROCESS/OPERATIONAL RESTRICTIONS

- The permittee shall not operate equipment located in EUCR3173-S3 in vacuum service, while processing a VOC, unless a vacuum pump connected to the thermal oxidizer control is installed and operated properly.² (**R 336.1702, R 336.1910**)
- 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 manner in compliance with all applicable state rules and federal regulations (R 336.1224, R336.1225, R 336.1702(a))

App No. 202400018

Section 3 – Active Pharmaceutical Ingredients (API)

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

4.3. The permittee shall handle all materials for EUCR3173-S3 activities containing volatile compounds other than water in a manner to minimize the generation of fugitive emissions. The permittee shall keep containers covered at all times except when operator access is necessary. (R 336.1224, R 336.1225, R 336.1702(a))

Section 3 – Active Pharmaceutical Ingredients (API)

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

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))

1. ~~Upon request of the AQD District Supervisor, the permittee shall verify the PM emissions rates from EUCR3173-S3 by testing at the owner's expense, in accordance with Department requirements. Testing shall be performed using an approved EPA Method listed in 40 CFR Part 60, Appendix A and/or Part 10 of the Michigan Air Pollution Control Rules. An alternate method, or a modification to the approved EPA Method, may be specified in an AQD approved Test Protocol and must meet the requirements of the federal Clean Air Act, all applicable state and federal rules and regulations, and be within the authority of the AQD to make the change. No less than 30 days prior to testing, the permittee shall submit a complete test plan to the AQD Technical Programs Unit and District Office. The AQD must approve the final plan prior to testing, including any modification to the method in the test protocol that are proposed after initial submittal. The permittee must submit a complete report of the test results to the AQD Technical Program Unit and District Office within 60 days following the last date of the test. (R 336.1225, R 336.1331, R 336.2001, R 336.2003, R 336.2004).~~

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VI. MONITORING/RECORDKEEPING

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

- 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 336.1702(a), R 336.1910)
- The permittee shall calculate and record the actual particulate 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))

See Appendix 4-S3

VII. REPORTING

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

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. SVC173HBEX6	10 ²	42 ²	R 336.1225, 40 CFR 52.21(c)&(d)
2. SVC173HBEX25	14 ²	45 ²	R 336.1225, 40 CFR 52.21(c)&(d)

Section 3 – Active Pharmaceutical Ingredients (API)

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

Flexible Group ID	Flexible Group Description	Associated Emission Unit IDs
FGCRALLTOX-S3	All of the equipment located in Region I, Process Buildings 38, 127, 155, 195; Region II, Process Buildings 44, 149; Region III, Process Buildings 73, 173, 207, 225; and Region IV, Process Buildings 66, 76, 91 commercial, 172, 335, <u>and Region VI process Building 38</u> that is "connected" to the regional TOX.	EUCR138-S3 EUCR1127-S3 EUCR1155-S3 EUCR1195-S3 EUCR244-S3 EUCR2149-S3 EUCR373-S3 EUCR3173-S3 EUCR3207-S3 EUCR3225-S3 EUCR466-S3 EUCR476-S3 EUCR491COM-S3 EUCR4172-S3 EUCR4335-S3 EUC38R6ALL-S3
FGCR6FERM-S3	Fermentation processes common to Buildings 38 and 121.	EUC121R6ALL-S3 EUC38R6ALL-S3
FGCFUG-S3	Pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, control devices, and closed vent systems intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year, subject to regulation for equipment leaks under 40 CFR Part 63, Subpart GGG.	EUCR138-S3 EUCR1127-S3 EUCR1155-S3 EUCR1166-S3 EUCR1195-S3 EUCR244-S3 EUCR2149-S3 EUCR373-S3 EUCR3173-S3 EUCR3207-S3 EUCR3225-S3 EUCR466-S3 EUCR476-S3 EUCR491COM-S3 EUCR4335-S3 EUCR4172-S3 EUC38R6ALL-S3 EUC120R6ALL-S3 EUC121R6ALL-S3

Section 3 – Active Pharmaceutical Ingredients (API)

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

**FGCRALLTOX-S3
 FLEXIBLE GROUP CONDITIONS**

DESCRIPTION

All of the equipment located in Region I process Buildings 38, 127, 155, 195; Region II process Buildings 44, 149; Region III process Buildings 73, 173, 207, 225; and Region IV process Buildings 66, 76, 91 commercial, 172, 335 and [Region VI process Building 38](#) that is "connected" to the regional TOX.

Emission Units: EUCR138-S3, EUCR1127-S3, EUCR1155-S3, EUCR1195-S3, EUCR244-S3, EUCR2149-S3, EUCR373-S3, EUCR3173-S3, EUCR3207-S3, EUCR3225-S3, EUCR466-S3, EUCR476-S3, EUCR491COM-S3, EUCR4172-S3, EUCR4335-S3, EUC38R6ALL-S3

POLLUTION CONTROL EQUIPMENT

Thermal Oxidizer System - (two parallel thermal oxidizer, quench, and scrubber trains-one in use and one as a backup).

I. EMISSION LIMIT(S)

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Other VOC (VOCs, Methylene Chloride and Acetone)	20 ppmv TOC as methane ²	24-hour average	Thermal oxidizer	SC VI.8	R 336.1225, R 336.1702(a), R 336.1901, 40 CFR 63.1258(b)(8)(iii)
2. Other VOC	37 tons ²	12-month rolling time period as determined at the end of each calendar month	Thermal oxidizer	SC VI.9	40 CFR 52.21
3. OVC (toxic air contaminants, as defined in Rule 120, other than methylene chloride, acetone and other VOC)	16 pph ¹	Before control with a thermal oxidizer	All Region I buildings combined	SC VI.10	R 336.1224, R 336.1225
4. OVC	30 pph ¹	Hourly, Before control with a thermal oxidizer	All Region II buildings combined	SC VI.10	R 336.1224, R 336.1225
5. OVC	113 pph ¹	Hourly, Before control with a thermal oxidizer	All Region III buildings combined	SC VI.10	R 336.1224, R 336.1225
6. OVC	38 pph ¹	Hourly, Before control with a thermal oxidizer	All Region IV buildings combined	SC VI.10	R 336.1224, R 336.1225
7. OVC	21 pph ¹	Hourly, After control	Thermal oxidizer	SC VI.8	R 336.1224, R 336.1225
8. HCl	27 pph ¹	Hourly, After control	Thermal oxidizer, scrubber	SC VI.8	R 336.1225
9. HCl	95% reduction in emissions	Hourly	Thermal oxidizer, scrubber	SC VI.8	40 CFR 63.1252(g)(1)