



Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

Via FedEx # 7787 6934 5285 and Email [EGLE-ROP@michigan.gov]

August 26, 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. 109-24

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. 109-24 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,

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

Jill June
Site Leader – Kalamazoo

PGS
Global Sterile Injectables

cc/att: Michael Cox – Email Only [cox9@michigan.gov]



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 			Date 9/26/2024	



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 - <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> <input type="checkbox"/> Rule 215(1) Notification of change. Complete Items 8 – 10 and 14 <input type="checkbox"/> Rule 215(2) Notification of change. Complete Items 8 – 10 and 14 <input type="checkbox"/> Rule 215(3) Notification of change. Complete Items 8 – 11 and 14 <input type="checkbox"/> Rule 215(5) Notification of change. Complete Items 8 – 10 and 14 <input type="checkbox"/> Rule 216(1)(a)(i)-(iv) Administrative Amendment. Complete Items 8 – 10 and 14 <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. <input checked="" type="checkbox"/> Rule 216(2) Minor Modification. Complete Items 8 – 12 and 14 <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. <input type="checkbox"/> Rule 216(4) State-Only Modification. Complete Items 8 – 12 and 14		
8. Effective date of the change. (MM/DD/YYYY) <i>See detailed instructions.</i> 09/27/2024		9. Change in emissions? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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> Incorporate updated requirement for permit to install (PTI) 109-24. Allow for new condition in issue PTI to be used.		
11. New Source Review Permit(s) to Install (PTI) associated with this application? If Yes, enter the PTI Number(s) 109-24 - - - - -		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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 Timothy Swainston	Telephone No. 269-833-0080	E-mail Address 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



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
EUCR466-S3	All equipment in or around Building 66 located in API Region IV.	01-01-1951/ 12-28-1995/ <u>9/27/2024</u>	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR476-S3	All equipment in or around Building 76 located in API Region IV.	01-01-1954/ 12-28-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR491COM-S3	All equipment in or around Building 91, commercial area, located in KAPI Region IV.	01-01-1961/ 12-28-1995/ 03-31-2015 08-27-2021 01-31-2022	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR4172-S3	Storage tanks in or around Building 172 located in API Region IV.	01-01-1967/ 12-28-1995	FGCRALLTOX-S3 FGPHARMAMACT-S3 FGCFUG-S3
EUCR4335-S3	All equipment in or around Building 335 located in API Region IV (PTI No. 21-19). Particulate emissions are controlled by a number of pollution control equipment, including a new dust collector (335DUST5000-1).	01-01-1991/ 08-14-1996/ 04-15-2019	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUC38R6ALL-S3	Equipment in or around building 38, (located in API Region VI), used to manufacture fermentation intermediates and products, which includes the installation of two replacement acetone tanks (ID#TANK1022-1 and TANK1022-2). Emissions from the replacement tanks are controlled by a thermal oxidizer.	01-01-1946/ 11-30-2010/ 10-23-2017/ 05-21-2018/ 9-21-2020	FGCRALLPART-S3 FGCR6FERM-S3 FGCFUG-S3 FGPHARMAMACT-S3 FGCRALLTOX-S3
EUC120R6ALL-S3	Equipment in or around Building 120, part of API region VI, used to manufacture fermentation intermediates and products. Also includes the silos.	01-01-1962/ 07-31-1996	FGCRALLPART-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUC121R6ALL-S3	Equipment in or around Building 121, part of API region VI, used to manufacture fermentation intermediates and products.	01-01-1962/ 07-31-1996/ 10-23-2017 04-30-2018	FGCR6FERM-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUC41MICH33-S3	Exhaust hood in micronizing in B41.	09-01-2006	FGRULE290-S3
EUC76TIS254-S3	UIC surge tank.	01-01-1980	FGRULE290-S3
EUCR1127CENTRIFUGE-S3	Centrifuge.	01-01-2003	FGRULE290-S3
EUCR1127CLEANING-S3	Cleaning station.	01-01-2005	FGRULE290-S3
EUCR1127FILT1268-S3	Sparkler filter.	01-01-2002	FGRULE290-S3
EUCR1155CLEANING-S3	Cleaning station.	01-01-2007	FGRULE290-S3
EUCR1195OT380-S3	Storage tank.	01-01-1971	FGRULE290-S3
EUCR1195SHKRA-S3	Shaker separator.	01-01-1971	FGRULE290-S3
EUCR1195HKRB-S3	Shaker separator.	01-01-1971	FGRULE290-S3

Section 3 – Active Pharmaceutical Ingredients (API)

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

**EUCR466-S3
 EMISSION UNIT CONDITIONS**

DESCRIPTION

All equipment in or around Building 66. Located in API Region IV.

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

POLLUTION CONTROL EQUIPMENT

HEPA Filter on ~~FILT~~FANE119, FANE1120 FILT3114, dry filter HEPE1517 in line to SCRB1001, and FILT1543; Condensers connected to TOX.

I. EMISSION LIMITS

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Particulate	475 lbs ¹	Per month	All process vents combined	SC VI.1	R 336.1225, R 336.1227(2)
2. Particulate	Limits in the table below: ²	Hourly	EUCR466-S3	SC VI.1	R 336.1225, R 336.1331(e)

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. FANE1119 FILT4	0.6042	0.4330	0.2618	0.00913	0.0107	0.0021	104,000
4. FANE1120	0.18	0.13	0.08	0.004	0.003	0.0006	600
54. SCRB1001	0.21	0.10	0.05	0.008	0.004	0.002	6,000
65. FILT3114	0.02	0.01	0.01	0.013	0.010	0.006	250
76. FILT1543	0.39	0.28	0.17	0.013	0.010	0.006	6,500

II. MATERIAL LIMITS

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Lots of product produced in TSP processes.	190 lots ¹	Per month	EUCR466-S3	SC VI.1	R 336.1225, R 336.1227(2)

III. PROCESS/OPERATIONAL RESTRICTIONS

- The permittee shall not operate equipment located in EUCR466-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 336.1224, R 336.1910)

IV. DESIGN/EQUIPMENT PARAMETER(S)

NA

Section 3 – Active Pharmaceutical Ingredients (API)

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

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 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(e))

See Appendix 4-S3

VII. REPORTING

1. Prompt reporting of deviations pursuant to General Conditions 21 and 22 of Part A. (R 336.1213(3)(c)(ii))
2. 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))
3. 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. SVC66FANE1119\LT1	32 ²⁰ ¹	58 ⁷ ¹	R 336.1225 40 CFR 52.21(c) & (d)
2. SCV66FANE1120	8	52	R 336.1225 40 CFR 52.21(c) & (d)
2. SVC66SCRB1001	16 ¹	80 ¹	R 336.1225 40 CFR 52.21(c) & (d)
3. SVC66FILT3114	5 ¹	50 ¹	R 336.1225 40 CFR 52.21(c) & (d)
4. SVC66FILT1543	24 ¹	50 ¹	R 336.1225 40 CFR 52.21(c) & (d)

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IX. OTHER REQUIREMENT(S)

NA

Footnotes:

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

Section 3 – Active Pharmaceutical Ingredients (API)

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

Rotoclone/ Scrubber	Fabric Filter	Emission Unit	Acceptable min/max or min GPM water	Acceptable minimum water pressure (psi)	Acceptabl e min/max differential pressure (inches of water)	Acceptable minimum water level (inches)
EX-OT354		EUCR138-S3				1
	DUST1018	EUCR138-S3			0.6/8	
127ROTO3127-1		EUCR1127-S3		40		
127ROTO3128-1		EUCR1127-S3		40		
SCRB1044		EUCR1155-S3	30/70			7
EX-OT356		EUCR1166-S3				1
EX-T288		EUCR1166-S3				1
EX-T289		EUCR1166-Se				1
EX-17		EUCR1195-S3		40		
EX-19		EUCR1195-S3			0.1/10	
EX-31		EUCR244-S3		40		
EX-9		EUCR2149-S3		40		
EX-10		EUCR2149-S3		40		
EX-28		EUCR2149-S3		40		
SCRB-1003		EUCR2149-S3	40/100			
SCRB-1004		EUCR2149-S3	120/200			
SCRB-1005		EUCR2149-S3	70/150			
	DUST1008	EUCR373-S3			0.2/5.0	
EX-6		EUCR3173-S3		40		
EX-25		EUCR3173-S3		40		
EX-34		EUCR3173-S3		40		
SCRB1002		EUCR3173-S3	300/400			
	DC1/207	EUCR3207-S3			0.2/5.0	
SCRB1036		EUCR3207-S3	52/132 upper nozzle			
SCRB1036		EUCR3207-S3	52/132 lower nozzle			
SCRB1006		EUCR3225-S3	175/275			
SCRB1007		EUCR3225-S3	75/150			
	EF1C1HB1	EUCR3225-S3			0.1/2.5	
	EX-27	EUCR3225-S3			0.1/2.5	
	EX-30	EUCR3225-S3			0.1/2.5	
	EX-34	EUCR3225-S3			0.1/2.5	
	FANE1119	EUCR466-S3			0.05/2.50 70 min	
	FANE1120	EUCR466-S3			0.05/2.5	
	FILT3114	EUCR466-S3			0.1/2.5	
	FILT1543	EUCR466-S3			0.1/2.5	
	HEPE1517	EUCR466-S3			0.1/2.5	
EX-23		EUCR476-S3		15		
	DUST1010	EUCR491COM-S3			2.0/12.0	
	EX-27 1049	EUCR491COM-S3			0.1/2.5	
	EX-27 1056	EUCR491COM-S3			0.1/2.5	
	EX-117	EUCR491COM-S3			0.1/3	
	EX-118	EUCR491COM-S3			0.1/3	