



Pfizer Inc  
7000 Portage Road  
Kalamazoo, MI 49001-0199

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**Pfizer Global Supply**

February 9, 2023

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. 23-23

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. 23-23 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](mailto:Timothy.Swainston@pfizer.com).

Sincerely,

A handwritten signature in blue ink, appearing to read 'David Breen'.

**David Breen**  
Site Leader – Kalamazoo

**PGS**  
Global Sterile Injectables

Email and FedEx # 7712 5199 8491

cc/att: Monica Brothers – 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.*

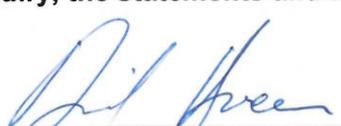
**This form is completed and included as part of Renewable Operating Permit (ROP) initial and renewal applications, notifications of change, amendments, modifications, and additional information.**

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

<b>SUBMITTAL CERTIFICATION INFORMATION</b>	
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 <b>-001</b>	

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

<b>This form must be signed and dated by a Responsible Official.</b>				
Responsible Official Name David Breen			Title Site Leader	
Mailing address 7000 Portage Rd.				
City Kalamazoo	State MI	ZIP Code 49001	County Kalamazoo	Country United States
<b>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.</b>				
 _____ Signature of Responsible Official			<u>02/09/2023</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	
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> 02/10/2023	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 requirements for PTI 23-23. Allow startup of the TANK3418 and TANK3419 located in B91.		
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) 23-23		
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

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
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### 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

**EUCR491COM-S3  
 EMISSION UNIT CONDITIONS**

**DESCRIPTION**

All equipment in or around Building 91, commercial area, located in API Region IV.

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

**POLLUTION CONTROL EQUIPMENT**

HEPA Filters on DUST1010, EX27 filters1049 and 1056, EX117, EX118, EX119, Exhaust Fans on EX107, EX124; Condensers, connected to TOX; Scrubbers, connected to TOX.

**I. EMISSION LIMITS**

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. VOC	50 lbs <i>per month</i> <sup>1</sup>	<i>Calendar Per</i> month	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
2. VOC	10 lbs <i>per lot</i> <sup>1</sup>	<i>Each Per</i> lot	Unconnected VOC processes	SC VI.3	R 336.1225, R 336.1227(2)
3. Methanol	0.1 pph <sup>1</sup>	Hourly	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
4. Methylene Chloride	1 pph <sup>1</sup>	Hourly	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
5. Ozone	0.2 pph <sup>1</sup>	Hourly	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
6. Particulate	90 lbs <i>per month</i> <sup>1</sup>	<i>Calendar Per</i> month	All process vents combined	SC VI.2	R 336.1225, R 336.1227(2)
7. Particulate	Limits in the table below: <sup>2</sup>	Hourly	EUCR491COM-S3	SC VI.2	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	
8. DUST1010	0.19	0.13	0.08	0.01	0.01	0.006	3,090
9. EX-27	0.23	0.17	0.10	0.01	0.01	0.006	4,000
10. EX-107	-	1.44	0.86	-	0.10	0.06	3,360
11. EX-117	0.06	0.043	0.026	0.01	0.01	0.006	1,000
12. EX-118	0.06	0.043	0.026	0.01	0.01	0.006	1,000
13. EX-119	0.06	0.043	0.026	0.01	0.01	0.006	1,000
14. EX-124	-	1.37	0.82	-	0.10	0.06	3,200

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

## Section 3 – Active Pharmaceutical Ingredients (API)

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

**II. MATERIAL LIMITS**

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Lots of product produced in TSP processes.	30 lots <del>per</del> month <sup>1</sup>	<del>Calendar</del> - <del>Per</del> month	EUCR491COM-S3	SC VI.65	R 336.1225, R 336.1227(2)
2. Lots of VOC emitting product produced in equipment not controlled by the thermal oxidizer	5 lots <del>per</del> month <sup>1</sup>	<del>Calendar</del> - <del>Per</del> month	EUCR491COM-S3	SC VI.67	R 336.1225, R 336.1227(2)

**III. PROCESS/OPERATIONAL RESTRICTIONS**

- The permittee shall not operate equipment located in EUCR491COM-S3 in vacuum service, while processing a VOC, unless a vacuum pump connected to the thermal oxidizer control is installed, maintained, and operated in a satisfactory manner acceptable to the AQD District Supervisor.<sup>2</sup> (R 336.1224, R 336.1910)
- The permittee shall capture all waste materials from the solvent cleaning of the lipid storage tanks 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.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))
- The permittee shall handle all materials for EUCR491COM-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.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))

**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))

- The permittee shall complete all required calculations in a format acceptable to the AQD District Supervisor by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition.<sup>2</sup> (R 336.1225, ~~R 336.1227(2)~~, R 336.1331(c), 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.<sup>2</sup> (R 336.1225, R 336.1227(2), R 336.1331(c))
- The permittee shall calculate the actual VOC emissions from each process for unconnected VOC equipment for each calendar month using the method detailed in Appendix 4-S3.<sup>2</sup> (R 336.1702(a))
- ~~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.<sup>2</sup> (R 336.1225, R 336.1702(a), R 336.1331(c), R 336.1910)~~

Section 3 – Active Pharmaceutical Ingredients (API)

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

- 5.4. 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.<sup>2</sup> (R 336.1331)
- 6.5. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in PM-emitting activities in EUCR491COM-S3 on a calendar month basis.<sup>1</sup> (R 336.1225, R 336.1227(2))
- 7.6. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in VOC-emitting activities in EUCR491COM-S3 on a calendar month basis.<sup>1</sup> (R 336.1225, R 336.1227(2))

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. SVC91EX107	16 <sup>2</sup>	23 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)
2. SVC91EX117	10 <sup>2</sup>	23 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)
3. SVC91EX118	10 <sup>2</sup>	23 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)
4. SVC91EX119	10 <sup>2</sup>	23 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)
5. SVC91EX124	18 <sup>2</sup>	40 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)
6. SVC91EX27*	25 x 19 <sup>2</sup>	37 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)
7. SVC91DUST1010	24 <sup>2</sup>	62 <sup>2</sup>	R 336.1225 40 CFR 52.21(c)&(d)

\* may have an orientation 45° below horizontal

Commented [ST1]: Submitted the letter for modify the emission unit at the same time so this requirement is no longer applicable.