

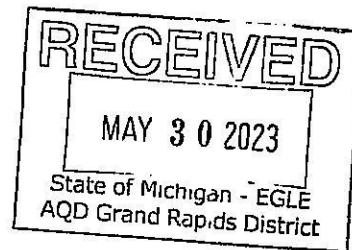


Pfizer Inc  
7000 Portage Road  
Kalamazoo, MI 49001-0199

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**Pfizer Global Supply**

May 25, 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. 4-22

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. 4-22 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 Nathan Lucas at 269.833.2007 or [Nathan.Lucas@pfizer.com](mailto:Nathan.Lucas@pfizer.com).

Sincerely,

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

**David Breen**  
Site Leader – Kalamazoo

**PGS**  
Global Sterile Injectables

Email and FedEx # 7722 2732 6546

cc/att: Monica Brothers – Email Only

Bcc: Central File 7.10.12  
W. Eric Ferrell – Pfizer Kalamazoo – Email Only  
Steve Maynard – Pfizer Kalamazoo – Email Only  
Tim Swainston – Pfizer Kalamazoo – Email Only  
Nathan Lucas – Pfizer Kalamazoo – Email Only  
DOC ID: \\KZOUNS600VFS01\kzo-ehs\_share\_drive\ENVIRONMENTAL\Air  
\_Program\Renewable\_Operating\_Permit\Updates\Updates\_2023\B38\_PTI\_4-22\_T-217  
Receiver\ROP\_MOD\_Letter\_B38\_PTI\_4-22\_T-217 Receiver.docx



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. <i>Complete Items 8 – 10 and 14</i></p> <p><input type="checkbox"/> Rule 215(2) Notification of change. <i>Complete Items 8 – 10 and 14</i></p> <p><input type="checkbox"/> Rule 215(3) Notification of change. <i>Complete Items 8 – 11 and 14</i></p> <p><input type="checkbox"/> Rule 215(5) Notification of change. <i>Complete Items 8 – 10 and 14</i></p> <p><input type="checkbox"/> Rule 216(1)(a)(i)-(iv) Administrative Amendment. <i>Complete Items 8 – 10 and 14</i></p> <p><input type="checkbox"/> Rule 216(1)(a)(v) Administrative Amendment. <i>Complete Items 8 – 14. Results of testing, monitoring &amp; recordkeeping must be submitted. See detailed instructions.</i></p> <p><input checked="" type="checkbox"/> Rule 216(2) Minor Modification. <i>Complete Items 8 – 12 and 14</i></p> <p><input type="checkbox"/> Rule 216(3) Significant Modification. <i>Complete Items 8 – 12 and 14, and provide any additional information needed on ROP application forms. See detailed instructions.</i></p> <p><input type="checkbox"/> Rule 216(4) State-Only Modification. <i>Complete Items 8 – 12 and 14</i></p>		
8. Effective date of the change. (MM/DD/YYYY) <i>See detailed instructions.</i> <u>05/26/2023</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 4-22. Allow startup of the T-217 Receiver located in B38.</p>		
<p>11. New Source Review Permit(s) to Install (PTI) associated with this application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, enter the PTI Number(s) <u>4-22</u> - - - - -</p>		
<p>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></p> <p>a. Is the change identified above in compliance with the associated applicable requirement(s)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>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</p> <p>c. If the change includes a future applicable requirement(s), will timely compliance be achieved? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>		
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 Nathan Lucas	Telephone No. 269-833-2007	E-mail Address nathan.lucas@pfizer.com
<p>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></p>		

**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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Pages in PTI 4-22 and the corresponding pages in ROP No. MI-ROP-B3610-2021a are identical and no modifications needed to ROP.



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

<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 -001	

<b>CONTACT INFORMATION</b>	
Contact Name Nathan Lucas	Title Senior EHS Specialist - Environmental
Phone number 269-833-2007	E-mail address nathan.lucas@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
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			_____ 05/23/23 Date	

Section 3 – Active Pharmaceutical Ingredients (API)

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

**EUCR138-S3  
 EMISSION UNIT CONDITIONS**

**DESCRIPTION**

All equipment in or around Building 38. Located in API Region I. Particulate emissions are controlled by a number of pollution control equipment, including a new W-Rotoclone (038ROTO0214-1).

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

**POLLUTION CONTROL EQUIPMENT**

W-Rotoclones on EX104, 038ROTO0214-1; N-Rotoclones on EXT245, EXOT354; Exhaust Fan on EX216, EX309, EX310, EX316, EX322; Dust Collector on DUST1018; Condensers, connected to TOX (thermal oxidizer).

**I. EMISSION LIMITS**

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Particulate matter (PM)	1180 lbs/month <sup>1</sup>	Calendar month	All process vents combined	SC VI.2	R 336.1225, R 336.1227(2)
2. PM	Limits in the table below: <sup>2</sup>	Hourly	All EUCR373-S3 vents combined	SC VI.2	R 336.1225, 40 CFR 52.21(c)&(d)
3. PM10	1,180 lbs/month <sup>1</sup>	Calendar month	All process vents combined	SC VI.2	R 336.1225, R 336.1227(2)
4. PM10	Limits in the table below: <sup>2</sup>	Hourly	All EUCR373-S3 vents combined	SC VI.2	R 336.1225, 40 CFR 52.21(c)&(d)
5. PM2.5	1,180 lbs/month <sup>1</sup>	Calendar month	All process vents combined	SC VI.2	R 336.1225, R 336.1227(2)
6. PM2.5	Limits in the table below: <sup>2</sup>	Hourly	All EUCR373-S3 vents combined	SC VI.2	R 336.1225, 40 CFR 52.21(c)&(d)

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	
1. EX-104	1.30	0.33	0.33	0.08	0.02	0.02	3,800
2. 038ROTO0214-1	-	0.36	0.36	-	0.02	0.02	4,250
3. EX-216	-	0.52	0.31	-	0.10	0.06	1,222
4. EX-T245	0.49	0.12	0.12	0.08	0.02	0.02	1,416
5. EX-309	-	1.18	0.71	-	0.10	0.06	2,750
6. EX-310	-	1.54	0.93	-	0.10	0.06	3,600
7. EX-316	-	2.00	1.20	-	0.10	0.06	4,660
8. EX-322	-	0.91	0.55	-	0.10	0.06	2,130
9. EX-OT354	0.49	0.12	0.12	0.08	0.02	0.02	1,416
10. DUST1018	0.29	0.21	0.12	0.01	0.01	0.01	4,800

<sup>1</sup>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	295 lots/month <sup>1</sup>	Calendar month	All process vents combined	SC VI,3	R 336.1225, R 336.1227(2)

2. The permittee shall not exhaust particulate emissions from the handling of category size A materials in EUCR138-S3 through the W-Rotoclone (038ROTO0214-1).<sup>2</sup> (R 336.1225, 40 CFR 52.21(c) and (d))

**III. PROCESS/OPERATIONAL RESTRICTION**

1. The permittee shall not operate equipment located in EUCR138-S3 in vacuum service, while processing a VOC, unless a vacuum pump connected to the thermal oxidizer control is installed and operated properly.<sup>2</sup> (R 336.1224, R 336.1910)

**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 calculations/records 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 336.1702(a), 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.<sup>2</sup> (R 336.1225, 40 CFR 52.21(c)&(d))
3. The permittee shall monitor and record, in a satisfactory manner, the number of lots of material produced in PM-emitting processes run in EUCR138-S3 on a calendar month basis.<sup>1</sup> (R 336.1225, R 336.1227(2))
4. The permittee shall monitor and record, in a satisfactory manner, the mean particle size and category of each lot of processed material controlled through the W-Rotoclone (038ROTO0214-1) on a calendar month basis. The permittee shall keep the records on file at the facility, in a format acceptable to the AQD District Supervisor, and make them available to the Department upon request.<sup>2</sup> (R 336.1225, 40 CFR 52.21(c) and (d))

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))

Commented [LN1]: Requirement VII(1) from PTI 4-22 is no longer applicable. Modification completion notification was submitted at the same time as the ROP modification.

Section 3 – Active Pharmaceutical Ingredients (API)

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

- 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. SVC38EX104	14 <sup>2</sup>	56 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
2. SV038ROTO0214-1	28 <sup>2</sup>	60 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
3. SVC38EX216	8 <sup>2</sup>	43 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
4. SVC38EX309	14 <sup>2</sup>	55 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
5. SVC38EX310	14 <sup>2</sup>	55 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
6. SVC38EX316	22 <sup>2</sup>	50 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
7. SVC38EX322	20 <sup>2</sup>	45 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
8. SVC38DUST1018*	47 <sup>2</sup>	45	R 336.1225, 40 CFR 52.21 (c)&(d)
9. SVC38EXOT354**	9 <sup>2</sup>	47.5 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)
10. SVC38EXT245**	9 <sup>2</sup>	52 <sup>2</sup>	R 336.1225, 40 CFR 52.21 (c)&(d)

- \* may be discharged horizontally
- \*\* may be discharged with a rain cap

**IX. OTHER REQUIREMENT(S)**

- The permittee shall comply with all applicable provisions of the National Emission Standards for Hazardous Air Pollutants, as specified in 40 CFR Part 63, Subparts A and GGG for Pharmaceuticals Production by the initial compliance date.<sup>2</sup> (40 CFR Part 63, Subparts A and GGG)

**Footnotes:**

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