



Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

March 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. 103-22

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. 103-22 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 Tim Swainston at 269.833.0080 or 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 # 7714 8011 9880

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.

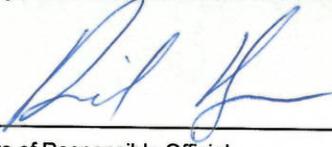
This form is completed and included as part of Renewable Operating Permit (ROP) initial and renewal applications, notifications of change, amendments, modifications, and additional information.

| | |
|-----------------|-----------|
| Form Type 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 <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 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 | | | <u>03/09/2023</u> Date | |



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 & 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>03/10/2023</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 103-22. Allow startup of the SCRB1047-1 located in B120.</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>103-22</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

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/ Modificatio n Date | Flexible Group ID |
|-----------------------|--|---|---|
| EUCR466-S3 | All equipment in or around Building 66 located in API Region IV. | 01-01-1951/ 12-28-1995 | 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/ <u>03-10-2023</u> | 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

| |
|--|
| EUC120R6ALL-S3 EMISSION UNIT CONDITIONS |
|--|

DESCRIPTION

Equipment in or around Building 120. Located in API Region VI.

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

POLLUTION CONTROL EQUIPMENT

Wet Venturi Scrubber on SCRB1047-1

I. EMISSION LIMITS

| Pollutant | Limit | Time Period/ Operating Scenario | Equipment | Monitoring/ Testing Method | Underlying Applicable Requirements |
|----------------|--|---------------------------------------|----------------|-------------------------------|--|
| 1. Particulate | 1,493 lbs ¹ | Per month | EUC120R6ALL-S3 | SC VI.24 | R 336.1225 |
| 2. Particulate | Limits in the table below: ² | Hourly | EUC120R6ALL-S3 | SC VI.24 | 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. SCRB1047 | 0.27 | 0.14 | 0.07 | 0.08 | 0.04 | 0.02 | 108,000 |

II. MATERIAL LIMITS

| Material | Limit | Time Period/ Operating Scenario | Equipment | Monitoring/ Testing Method | Underlying Applicable Requirements |
|---|-----------------------|---------------------------------------|----------------|-------------------------------|--|
| 1. Lots of product produced in TSP processes. | 279 lots ¹ | Per month | EUC120R6ALL-S3 | SC VI.32 | R 336.1225 |

III. PROCESS/OPERATIONAL RESTRICTION(S)

NA

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

Section 3 – Active Pharmaceutical Ingredients (API)

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

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 and 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. (R 336.1225, R 336.1227(2), R 336.1331(c))

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1-2. 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. The permittee shall keep all records on file at the facility and make them available to the Department upon request.² (R 336.1225, R 336.1227(2), R 336.1331(c))

3. On a monthly basis the permittee shall monitor and record, in a satisfactory manner, the actual lots produced in the EUC120R6ALL-S3 equipment on a monthly basis. The permittee shall keep all records on file at the facility and make them available to the Department upon request. (R 336.1225~~43(3)~~)

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2-4. The permittee shall monitor and keep a separate record for each calendar month of the Wet Venturi Scrubber SCRB1047-1 water flow rate. The readings shall be compared to the acceptable ranges detailed in Appendix 12-S3. The reading shall be performed once per calendar month during a period when the Wet Venturi Scrubber is being operated. (R 336.1225, R 336.1227(2), R 336.1331(c))

Commented [ST1]: Updated to match ROP reference as PTI 103-22 does not use ROP appendices.

See Appendix 4-S3 and Appendix 12-S3.

Commented [ST2]: Updated to match ROP reference as PTI 103-22 does not use ROP appendices.

VII. REPORTING

Commented [ST3]: SC VII.1 in PTI 103-22 in is no longer applicable as the letter was submitted to the EGLE district office the same day as this ROP modification was submitted.

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. SVC120R6SCRB1047 | 20 ¹ | 72 ¹ | R 336.1225 40 CFR 52.21(c) & (d) |

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

| Rotocloner/ 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) |
|-------------------------|-------------------|----------------|--|---|--|--|
| | DC22C | EUCR4335-S3 | | | 0.1/2.5 | |
| | DUST242 | EUCR4335-S3 | | | 0.1/2.5 | |
| | DC39 | EUCR4335-S3 | | | 0.1/2.5 | |
| | 335DUST5 000-1 | EUCR4335-S3 | | | 0.05/6.5 | |
| | FANE0210 -1 | EUCR4335-S3 | | | 0.2/3.0 | |
| SB180 | | EUCR4335-S3 | 132/475 | | | |
| SB385 | | EUCR4335-S3 | 20/50 | | | |
| | FILT0841-1 | EUCR4335-S3 | | | 0.1/4.0 | |
| | FILT0842-1 | EUCR4335-S3 | | | 0.1/4.0 | |
| | 335DUST3 007-1 | EUCR4335-S3 | | | 0.2/8.0 | |
| | DUST3010 | EUCR4335-S3 | | | 0.2/8.0 | |
| 038ROTO0217-1 | | EUC38R6ALL-S3 | | 40 | | |
| SCRB1047-1 | | EUC120R6ALL-S3 | 280/8100 | | | |