App #202200154

Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

August 8, 2022

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. 30-21A

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. 30-21A into the ROP No. MI-ROP-B3610-2021a. The affected emission unit is in Section 3 of the ROP. EUCR3173-S3 and EUCR3225-S3 have not been completed at this time.

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,

David Breen
Site Leader – Kalamazoo

PGS
Global Sterile Injectables

Email and FedEx # 7775 4000 4529

cc/att: Monica Brothers – Email Only

App #202200154

EGLE 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 *Check only one box.*

☐ Initial Application (Rule 210) ☒ Notification / Administrative Amendment / Modification (Rules 215/216)

☐ Renewal (Rule 210) ☐ Other, describe on AI-001

2. If this ROP has more than one Section, list the Section(s) that this Certification applies to 3

3. Submittal Media ☒ E-mail ☐ FTP ☐ Disk ☒ 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

08/08/22
Date

EGLE

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

App #202200154

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 - *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.*

- ☐ **Rule 215(1) Notification of change**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 215(2) Notification of change**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 215(3) Notification of change**. *Complete Items 8 – 11 and 14*
- ☐ **Rule 215(5) Notification of change**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 216(1)(a)(i)-(iv) Administrative Amendment**. *Complete Items 8 – 10 and 14*
- ☐ **Rule 216(1)(a)(v) Administrative Amendment**. *Complete Items 8 – 14. Results of testing, monitoring & recordkeeping must be submitted. See detailed instructions.*
- ☒ **Rule 216(2) Minor Modification**. *Complete Items 8 – 12 and 14*
- ☐ **Rule 216(3) Significant Modification**. *Complete Items 8 – 12 and 14, and provide any additional information needed on ROP application forms. See detailed instructions.*
- ☐ **Rule 216(4) State-Only Modification**. *Complete Items 8 – 12 and 14*

8. Effective date of the change. (MM/DD/YYYY) *See detailed instructions.* 08/09/2022	9. Change in emissions? ☐ Yes ☒ No

10. Description of Change - *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).*

Incorporate requirements for PTI 30-21A. Allow startup of the two solids drum handling glove boxes located in B149.

11. New Source Review Permit(s) to Install (PTI) associated with this application? ☒ Yes ☐ No

If Yes, enter the PTI Number(s) 30-21A ____-____ ____-____ ____-____ ____-____

12. Compliance Status - *A narrative compliance plan, including a schedule for compliance, must be submitted using an AI-001 if any of the following are checked No.*

a. Is the change identified above in compliance with the associated applicable requirement(s)? ☒ Yes ☐ No

b. Will the change identified above continue to be in compliance with the associated applicable requirement(s)? ☒ Yes ☐ No

c. If the change includes a future applicable requirement(s), will timely compliance be achieved? ☒ Yes ☐ No

13. Operator's Additional Information ID - *Create an Additional Information (AI) ID for the associated AI-001 form used to provide supplemental information.* **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 _____/_____/_____ ☐ Yes ☒ N/A
(If yes, a mark-up of the affected pages of the ROP must be attached.)

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

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

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/ 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-Rotoclone (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, which includes the installation of two (2) solids drum charging glove boxes (PTI No. 30-21A).	01-01-1965/ 06-01-1996 08-08-2022	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	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

EUCR2149-S3
EMISSION UNIT CONDITIONS

DESCRIPTION

All equipment in Building 149. Located in API Region II, which includes the installation of two (2) solids drum charging glove boxes. (PTI No. 30-21A)

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

POLLUTION CONTROL EQUIPMENT

W-Rotoclones on EX-9, EX-10, EX-28; Particle Scrubbers on SCRB-1003, SCRB-1004, SCRB-1005; Condensers connected to TOX.

I. EMISSION LIMITS

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Particulate	675 lbs[1]	Per month	All process vents combined	SC VI.21	**R 336.1225, R 336.1227(2)**
2. Particulate	Limits in the table below:[2]	Hourly	EUCR2149-S3	SC VI.21	**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
	A	B	C	A	B	C	(dscfm)
3. EX-9	0.44	0.11	0.11	0.08	0.02	0.02	1,285
4. EX-10	0.48	0.12	0.12	0.08	0.02	0.02	1,400
5. EX-28	0.48	0.12	0.12	0.08	0.02	0.02	1,400
6. SCRB1003	0.30	0.15	0.08	0.008	0.004	0.002	8,800
7. SCRB1004	0.82	0.41	0.21	0.008	0.004	0.002	24,000
8. SCRB1005	0.62	0.31	0.15	0.008	0.004	0.002	18,000

II. MATERIAL LIMITS

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Lots of product produced in TSP processes.	225 lots[1]	Per month	EUCR2149-S3	SC VI.21	**R 336.1225, R 336.1227(2)**

III. PROCESS/OPERATIONAL RESTRICTIONS

1. The permittee shall not operate equipment located in EUCR2149-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)**

2. 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

Formatted: Indent: Left: 0.25", No bullets or numbering

manner in compliance with all applicable state rules and federal regulations. (R 336.1224, R 336.1225, R 336.1702(a))

~~1.~~3. The permittee shall handle all materials for EUCR2149-S3 activities containing volatile compounds other than water in a manner to minimize the generation of fugitive emissions.

Formatted: List Paragraph, Left, No bullets or numbering

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 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. (R 336.1702(a), R 336.1910)

~~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.[2] **(R 336.1225, R 336.1227(2), R 336.1331(c))**

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. SVC149EX9	8~~+~~	49~~+~~	R 336.1225, 40 CFR 52.21(c) and (d)
2. SVC149EX10	8~~+~~	25~~+~~	R 336.1225, 40 CFR 52.21(c) and (d)
3. SVC149EX28	8~~+~~	46.5~~+~~	R 336.1225, 40 CFR 52.21(c) and (d)
4. SV149SCRB1003	20~~+~~	73~~+~~	R 336.1225, 40 CFR 52.21(c) and (d)
5. SV149SCRB1004	34~~+~~	73~~+~~	R 336.1225, 40 CFR 52.21(c) and (d)
6. SVC149SCRB1005	30~~+~~	73~~+~~	R 336.1225, 40 CFR 52.21(c) and (d)

IX. OTHER REQUIREMENT(S)

Formatted: Indent: Left: 0.25", No bullets or numbering

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Font: Not Bold