App #202400145

Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

Via FedEx # 7778 8818 5149 and Email [EGLE-ROP@michigan.gov]

August 14, 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. 98-24

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. 98-24 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,

Jill June
Site Leader – Kalamazoo

PGS
Global Sterile Injectables

cc/att: Michael Cox – Email Only

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 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.

J June — Signature of Responsible Official

8/14/2024 — Date

EGLE

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

App #202400145

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.* 08/15/2024	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 updated requirement for permit to install (PTI) 98-24. Allow for new condition in issue PTI to be used.

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

If Yes, enter the PTI Number(s) 98-24 ____-____ ____-____ ____-____ ____-____

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

App #202400145

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

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.

For Assistance
Contact: 800-662-9278

www.michigan.gov/egle

FGCR6FERM-S3
FLEXIBLE GROUP CONDITIONS

DESCRIPTION

Fermentation processes common to Buildings 38 and 121.

Emission Units: EUC38R6ALL-S3, EUC121R6ALL-S3

POLLUTION CONTROL EQUIPMENT

NA

I. EMISSION LIMITS

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. VOC and acetone	34.5 tpy [2]	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3 operations other than KCF production	SC VI.2	**R 336.1224, R 336.1702(a)**
2. VOC	45.7 tpy [2]	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.3	**R 336.1205(3)~~24~~ , R 336.1702(a)**
3. VOC	24.0 tons[2]	Calendar months April through September of each calendar year, as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.4	**40 CFR 52.21(d)**
4. Acetaldehyde	9.6 tons per year[1]	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.5	**R 336.1225(3)**
5. Formaldehyde	1.9 tons per year[1]	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.5	**R 336.1225(3)**

II. MATERIAL LIMIT(S)

1. The permittee shall not produce more than 14 lots of product code KCF in EUC121R6ALL-S3 per year, based on a 12-month rolling time period as determined at the end of each calendar month.[2] **(R 336.1205(3), R 336.1702(a))**

III. PROCESS/OPERATIONAL RESTRICTIONS

1. The permittee shall not exceed a maximum aeration rate of 150,000 standard cubic feet per minute supplied to all fermentation vessels combined.[2] **(R 336.2902)**

2. The permittee shall limit concurrent operations in FGCR6FERM-S3 as follows:[1] ~~**(R 336.1225)**~~
   a. No more than 13 fermentation operations for product code NM shall occur at the same time.

b. No more than 4 fermentation operations for product code AX or product code 1DF shall occur at the same time.
c. No more than 4 fermentation operations for product code KCF shall occur at the same time.

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 continuously monitor and record, in a satisfactory manner, the aeration rate supplied to all fermentation vessels combined during operation of FGCR6FERM-S3. Aeration rate data ~~monitoring shall consist~~must complete and record a minimum of one cycle operation (sampling and data recording) for each successive ~~of measurements made at least every~~ 15-minute ~~seconds~~ period during aeration and the maximum aeration rate shall be recorded once each calendar month that aeration occurs.[2] **(R 336.~~29021~~1205)**

2. To demonstrate compliance with SC I.1, the permittee shall calculate the VOC and acetone emission rate from FGCR6FERM-S3 operations other than KCF production monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request.[2] **(R 336.1702(a)~~, R 336.2902~~)**

3. To demonstrate compliance with SC I.2, the permittee shall calculate the VOC emission rate from FGCR6FERM-S3 monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request.[2] **(R 336.1205(3), R 336.1702(a))**

4. The permittee shall calculate the cumulative VOC emissions from FGCR6FERM-S3 monthly, for calendar months April through September of each calendar year, using a method acceptable to the AQD District Supervisor. The calculated emission total from a calendar year shall not carry forward to the next calendar year; the calculated emission total shall begin at zero each calendar year. The permittee shall keep all records on file at the facility and make them available to the Department upon request.[2] **(40 CFR 52.21(d))**

5. The permittee shall calculate the acetaldehyde and formaldehyde emission rates from FGCR6FERM-S3 monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request.[1] **(R 336.1225(3))**

6. To demonstrate compliance with SC III.2, the permittee shall keep the following records:[1] **(R 336.1225~~(3)~~)**
   a. The number of fermentation operations for product NM that occur during each calendar day.
   b. The number of fermentation operations for product AX and for product 1DF that occur during each calendar day.
   c. The number of fermentation operations for product KCF that occur during each calendar day.

7. The permittee shall keep a record for each lot of KCF produced in FGCR6FERM-S3, identifying the vessel and building in which the lot was produced.[1] **(R 336.1225)**

8. The permittee shall record the number of lots of product code KCF produced in EUC121R6ALL-S3 monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request.[2] **(R 336.1205(3))**