



Pfizer Inc
7000 Portage Road
Kalamazoo, MI 49001-0199

Pfizer Global Supply

Via FedEx

September 4, 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. 106-24

Dear EGLE ROP Team:

Attached, please find the M-001 form, C-001 Form and Permit to Install (PTI) required to incorporate Permit to Install (PTI) No. 106-24. The PTI will be incorporated into Section 3 of the renewable operating permit (MI-ROP-B3610-2021a).

If you need additional information or have any questions or concerns, please contact Bridget Grau at 269-833-3058 or Bridget.Grau@pfizer.com

Sincerely,

A handwritten signature in black ink that reads 'Jill June'.

This updated packet is for the previous submission on 8/28/2024.

Jill June
Site Leader – Kalamazoo

PGS
Global Sterile Injectables

cc/att: Monica Brothers – EGLE Kalamazoo District Office – Email Only [brothersm@michigan.gov]
Michael Cox – EGLE Kalamazoo District Office – Email Only [coxm9@michigan.gov]

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. <i>Complete Items 8 – 10 and 14</i> <input type="checkbox"/> Rule 215(2) Notification of change. <i>Complete Items 8 – 10 and 14</i> <input type="checkbox"/> Rule 215(3) Notification of change. <i>Complete Items 8 – 11 and 14</i> <input type="checkbox"/> Rule 215(5) Notification of change. <i>Complete Items 8 – 10 and 14</i> <input type="checkbox"/> Rule 216(1)(a)(i)-(iv) Administrative Amendment. <i>Complete Items 8 – 10 and 14</i> <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> <input checked="" type="checkbox"/> Rule 216(2) Minor Modification. <i>Complete Items 8 – 12 and 14</i> <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> <input type="checkbox"/> Rule 216(4) State-Only Modification. <i>Complete Items 8 – 12 and 14</i>		
8. Effective date of the change. (MM/DD/YYYY) <i>See detailed instructions.</i> 09/05/2024		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 106-24 into the renewable operating permit. To allow the charging of sodium metabisulfite in building 127.		
11. New Source Review Permit(s) to Install (PTI) associated with this application? If Yes, enter the PTI Number(s) 106-24 - - - - -		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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
14. Contact Name Bridget Grau	Telephone No. 269-833-3058	E-mail Address bridget.grau@pfizer.com
15. This submittal also updates the ROP renewal application submitted on ____/____/____ (If yes, a mark-up of the affected pages of the ROP must be attached.)		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> N/A

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

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

SUBMITTAL CERTIFICATION INFORMATION	
1. Type of Submittal. Check only one box.	
<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	

CONTACT INFORMATION	
Contact Name Bridget Grau	Title EHS Specialist - Environmental
Phone number 26-833-3058	E-mail address bridget.grau@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.				
Signature of Responsible Official			Date	

PERMIT TO INSTALL

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COMMON ACRONYMS

AQD	Air Quality Division
BACT	Best Available Control Technology
CAA	Clean Air Act
CAM	Compliance Assurance Monitoring
CEMS	Continuous Emission Monitoring System
CFR	Code of Federal Regulations
COMS	Continuous Opacity Monitoring System
Department/department/EGLE	Michigan Department of Environment, Great Lakes, and Energy
EU	Emission Unit
FG	Flexible Group
GACS	Gallons of Applied Coating Solids
GC	General Condition
GHGs	Greenhouse Gases
HVLP	High Volume Low Pressure*
ID	Identification
IRSL	Initial Risk Screening Level
ITSL	Initial Threshold Screening Level
LAER	Lowest Achievable Emission Rate
MACT	Maximum Achievable Control Technology
MAERS	Michigan Air Emissions Reporting System
MAP	Malfunction Abatement Plan
MSDS	Material Safety Data Sheet
NA	Not Applicable
NAAQS	National Ambient Air Quality Standards
NESHAP	National Emission Standard for Hazardous Air Pollutants
NSPS	New Source Performance Standards
NSR	New Source Review
PS	Performance Specification
PSD	Prevention of Significant Deterioration
PTE	Permanent Total Enclosure
PTI	Permit to Install
RACT	Reasonable Available Control Technology
ROP	Renewable Operating Permit
SC	Special Condition
SCR	Selective Catalytic Reduction
SNCR	Selective Non-Catalytic Reduction
SRN	State Registration Number
TBD	To Be Determined
TEQ	Toxicity Equivalence Quotient
USEPA/EPA	United States Environmental Protection Agency
VE	Visible Emissions

*For HVLP applicators, the pressure measured at the gun air cap shall not exceed 10 psig

POLLUTANT / MEASUREMENT ABBREVIATIONS

acfm	Actual cubic feet per minute
BTU	British Thermal Unit
°C	Degrees Celsius
CO	Carbon Monoxide
CO ₂ e	Carbon Dioxide Equivalent
dscf	Dry standard cubic foot
dscm	Dry standard cubic meter
°F	Degrees Fahrenheit
gr	Grains
HAP	Hazardous Air Pollutant
Hg	Mercury
hr	Hour
HP	Horsepower
H ₂ S	Hydrogen Sulfide
kW	Kilowatt
lb	Pound
m	Meter
mg	Milligram
mm	Millimeter
MM	Million
MW	Megawatts
NMOC	Non-Methane Organic Compounds
NO _x	Oxides of Nitrogen
ng	Nanogram
PM	Particulate Matter
PM ₁₀	Particulate Matter equal to or less than 10 microns in diameter
PM _{2.5}	Particulate Matter equal to or less than 2.5 microns in diameter
pph	Pounds per hour
ppm	Parts per million
ppmv	Parts per million by volume
ppmw	Parts per million by weight
psia	Pounds per square inch absolute
psig	Pounds per square inch gauge
scf	Standard cubic feet
sec	Seconds
SO ₂	Sulfur Dioxide
TAC	Toxic Air Contaminant
Temp	Temperature
THC	Total Hydrocarbons
tpy	Tons per year
µg	Microgram
µm	Micrometer or Micron
VOC	Volatile Organic Compounds
yr	Year

GENERAL CONDITIONS

1. The process or process equipment covered by this permit shall not be reconstructed, relocated, or modified, unless a Permit to Install authorizing such action is issued by the Department, except to the extent such action is exempt from the Permit to Install requirements by any applicable rule. **(R 336.1201(1))**
2. If the installation, construction, reconstruction, relocation, or modification of the equipment for which this permit has been approved has not commenced within 18 months, or has been interrupted for 18 months, this permit shall become void unless otherwise authorized by the Department. Furthermore, the permittee or the designated authorized agent shall notify the Department via the Supervisor, Permit Section, Air Quality Division, Michigan Department of Environment, Great Lakes, and Energy, P.O. Box 30260, Lansing, Michigan 48909-7760, if it is decided not to pursue the installation, construction, reconstruction, relocation, or modification of the equipment allowed by this Permit to Install. **(R 336.1201(4))**
3. If this Permit to Install is issued for a process or process equipment located at a stationary source that is not subject to the Renewable Operating Permit program requirements pursuant to Rule 210 (R 336.1210), operation of the process or process equipment is allowed by this permit if the equipment performs in accordance with the terms and conditions of this Permit to Install. **(R 336.1201(6)(b))**
4. The Department may, after notice and opportunity for a hearing, revoke this Permit to Install if evidence indicates the process or process equipment is not performing in accordance with the terms and conditions of this permit or is violating the Department's rules or the Clean Air Act. **(R 336.1201(8), Section 5510 of Act 451, PA 1994)**
5. The terms and conditions of this Permit to Install shall apply to any person or legal entity that now or hereafter owns or operates the process or process equipment at the location authorized by this Permit to Install. If the new owner or operator submits a written request to the Department pursuant to Rule 219 and the Department approves the request, this permit will be amended to reflect the change of ownership or operational control. The request must include all of the information required by subrules (1)(a), (b), and (c) of Rule 219 and shall be sent to the District Supervisor, Air Quality Division, Michigan Department of Environment, Great Lakes, and Energy. **(R 336.1219)**
6. Operation of this equipment shall not result in the emission of an air contaminant which causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property, or which causes unreasonable interference with the comfortable enjoyment of life and property. **(R 336.1901)**
7. The permittee shall provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of a hazardous or toxic air pollutant which continue for more than one hour in excess of any applicable standard or limitation, or emissions of any air contaminant continuing for more than two hours in excess of an applicable standard or limitation, as required in Rule 912, to the Department. The notice shall be provided not later than two business days after start-up, shutdown, or discovery of the abnormal condition or malfunction. Written reports, if required, must be filed with the Department within 10 days after the start-up or shutdown occurred, within 10 days after the abnormal conditions or malfunction has been corrected, or within 30 days of discovery of the abnormal condition or malfunction, whichever is first. The written reports shall include all of the information required in Rule 912(5). **(R 336.1912)**
8. Approval of this permit does not exempt the permittee from complying with any future applicable requirements which may be promulgated under Part 55 of 1994 PA 451, as amended or the Federal Clean Air Act.
9. Approval of this permit does not obviate the necessity of obtaining such permits or approvals from other units of government as required by law.
10. Operation of this equipment may be subject to other requirements of Part 55 of 1994 PA 451, as amended and the rules promulgated thereunder.

11. Except as provided in subrules (2) and (3) or unless the special conditions of the Permit to Install include an alternate opacity limit established pursuant to subrule (4) of Rule 301, the permittee shall not cause or permit to be discharged into the outer air from a process or process equipment a visible emission of density greater than the most stringent of the following. The grading of visible emissions shall be determined in accordance with Rule 303 (R 336.1303). **(R 336.1301)**
 - a) A six-minute average of 20 percent opacity, except for one six-minute average per hour of not more than 27 percent opacity.
 - b) A visible emission limit specified by an applicable federal new source performance standard.
 - c) A visible emission limit specified as a condition of this Permit to Install.
12. Collected air contaminants shall be removed as necessary to maintain the equipment at the required operating efficiency. The collection and disposal of air contaminants shall be performed in a manner so as to minimize the introduction of contaminants to the outer air. Transport of collected air contaminants in Priority I and II areas requires the use of material handling methods specified in Rule 370(2). **(R 336.1370)**
13. The Department may require the permittee to conduct acceptable performance tests, at the permittee's expense, in accordance with Rule 1001 and Rule 1003, under any of the conditions listed in Rule 1001. **(R 336.2001)**

EMISSION UNIT SPECIAL CONDITIONS

EMISSION UNIT SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Emission Unit ID	Emission Unit Description (Including Process Equipment & Control Device(s))	Installation Date / Modification Date	Flexible Group ID
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

Changes to the equipment described in this table are subject to the requirements of R 336.1201, except as allowed by R 336.1278 to R 336.1291.

EUCR1127-S3 EMISSION UNIT CONDITIONS

DESCRIPTION

All equipment in or around Building 127. Located in API Region I. (PTI No. 106-24)

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

POLLUTION CONTROL EQUIPMENT

Rotoclones on 127ROTO3127-1, 127ROTO3128-1.

I. EMISSION LIMIT(S)

Pollutant	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. Particulate matter (PM)	570 lbs per month ¹	Calendar month	All process EUCR1127-S3 vents combined	EUCR1127-S3, SC VI.1	R 336.1225, R 336.1227(2)
2. PM	Lbs per hour emission limit in the table below for the particle size category that applies to the materials used	Hourly	EUCR1127-S3	FGCRALLPART-S3, SC III.1 and III.3	R 336.1225, R 336.1331(c)
3. PM10	570 lbs per month	Calendar month	All EUCR1127-S3 vents combined	EUCR1127-S3, SC VI.1	40 CFR 52.21(c) and (d)
4. PM10	Lbs per hour emission limit in the table below for the particle size category that applies to the materials used	Hourly	EUCR1127-S3	FGCRALLPART-S3, SC III.1 and III.3	40 CFR 52.21(c) and (d)
5. PM2.5	570 lbs per month	Calendar month	All EUCR1127-S3 vents combined	EUCR1127-S3, SC VI.1	40 CFR 52.21(c) and (d)
6. PM2.5	Lbs per hour emission limit in the table below for the particle size category that applies to the materials used	Hourly	EUCR1127-S3	FGCRALLPART-S3, SC III.1 and III.3	40 CFR 52.21(c) and (d)

Emission Limits for PM, PM10, and PM2.5			
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)
1. EX-1	-	2.14	1.29	-	0.10	0.06	16,290
2. EX-2	-	2.74	1.65	-	0.10	0.06	6,400
3. 127ROTO3127-1	1.65	0.41	0.41	0.08	0.02	0.02	4,800
4. FANS1644	-	6.00	3.6	-	0.10	0.06	14,000
5. 127ROTO3128-1	0.89	0.22	0.22	0.076	0.019	0.019	2,600

II. MATERIAL LIMIT(S)

Material	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. Material produced in PM-emitting processes	152 lots per month ¹	Calendar month	EUCR1127-S3	SC VI.2	R 336.1225, R 336.1227(2)

III. PROCESS/OPERATIONAL RESTRICTION(S)

- The permittee shall not operate equipment located in EUCR1127-S3 in vacuum service, while processing a VOC, unless a vacuum pump connected to the thermal oxidizer control is installed and operated properly. (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 336.1201(3))

NA

VI. MONITORING/RECORDKEEPING

Records shall be maintained on file for a period of five years. (R 336.1201(3))

- The permittee shall calculate and record the actual PM, PM₁₀, and PM_{2.5} emission rates on a monthly basis using a method similar to that described in Appendix 4-S3. (R 336.1225, R 336.1227(2), R 336.1331(c), 40 CFR 52.21(c)&(d))
- The permittee shall monitor and record, in a satisfactory manner, the number of lots of material produced in PM-emitting processes run in EUCR1127-S3 on a calendar month basis.¹ (R 336.1225, R 336.1227(2))

See Appendix 4-S3

VII. REPORTING

NA

VIII. STACK/VENT RESTRICTION(S)

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 Diameter / Dimensions (inches)	Minimum Height Above Ground (feet)	Underlying Applicable Requirements
1. SVC127EX001	47 ¹	44 ¹	R 336.1225
2. SVC127EX002	36 ¹	42 ¹	R 336.1225
3. SV127ROTO3127-1	16	44	40 CFR 52.21(c) and (d), R 336.1225
4. SVC127FANS1644	52 ¹	49.3 ¹	R 336.1225
5. SV127ROTO3128-1	12 ¹	46 ¹	R 336.1225

IX. OTHER REQUIREMENT(S)

1. The permittee shall comply with all applicable requirements of the NESHAP (National Emission Standards for Hazardous Air Pollutants) for Pharmaceutical Production in 40 CFR Part 63, Subpart GGG. (40 CFR Part 63, Subpart GGG)

Footnotes:

- ¹ This condition is state only enforceable and was established pursuant to Rule 201(1)(b).

Appendix 4-S3. Recordkeeping

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR138-S3, EUCR1127-S3, EUCR1155-S3, EUCR1166-S3 and EUCR1195-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION I TSP PROCESSES			
Process Building	Particulate Maximum (lbs/lot)	Actual Number of lots/month	Estimated Particulate Emissions (lbs/month)
38	4		
127	3.75		
155	2.5		
166	0.5		
195	2		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR244-S3, and EUCR2149-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION II TSP PROCESSES			
Process Building	Particulate Maximum (lbs/lot)	Actual Number of lots/month	Estimated Particulate Emissions (lbs/month)
44	5.0		
149	3.0		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR373-S3, EUCR3173-S3, and EUCR3207-S3 and EUCR3225-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION III TSP PROCESSES			
Process Building	Particulate Maximum (lbs/lot)	Actual Number of lots/month	Estimated Particulate Emissions (lbs/month)
73	0.04		
173	1.6		
207	1.5		
225	1.64		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR466-S3 and EUCR491COM-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION IV TSP PROCESSES			
Process Building	Particulate Maximum (lbs/lot)	Actual Number of lots/month	Estimated Particulate Emissions (lbs/month)
66	2.5		
91 Commercial	2.5		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR476-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION IV TSP PROCESSES			
Process Building	Particulate Maximum (lbs/1000 lbs)	Actual Amount Charged lbs/month	Estimated Particulate Emissions (lbs/month)
76	0.000145		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUC38R6ALL-S3 and EUC120R6ALL-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION VI TSP PROCESSES			
Process Building	Particulate Maximum (lbs/lot)	Actual Number of lots/month	Estimated Particulate Emissions (lbs/month)
38	4.5		
120	5.35		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR3225-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION III UNCONNECTED VOC EQUIPMENT PROCESSES			
Process Building	VOC Maximum (lbs/lot)	Actual Number of lots/month	Estimated VOC Emissions (lbs/month)
225	2.5		

The permittee shall use the following approved formats and procedures for the recordkeeping requirements referenced in EUCR491COM-S3. Alternative formats must be approved by the AQD District Supervisor. An alternative format has been approved.

MONTHLY RECORDKEEPING FORMAT- REGION IV UNCONNECTED VOC EQUIPMENT PROCESSES			
Process Building	VOC Maximum (lbs/lot)	Actual Number of lots/month	Estimated VOC Emissions (lbs/month)
91	10		