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

State Registration Number		ROP Number
B3610	**RENEWABLE OPERATING PERMIT STAFF REPORT**	MI-ROP-B3610-2021a

Pharmacia & Upjohn Company, LLC

State Registration Number (SRN): B3610

Located at

7000 Portage Road, Kalamazoo, Kalamazoo County, Michigan 49001-0199

Permit Number:	MI-ROP-B3610-2021a
Staff Report Date:	July 26, 2021
Amended Date:	March 21, 2022

This Staff Report is published in accordance with Sections 5506 and 5511 of Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451). Specifically, Rule 214(1) of the administrative rules promulgated under Act 451, requires that the Michigan Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD), prepare a report that sets forth the factual basis for the terms and conditions of the Renewable Operating Permit (ROP).

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B3610

RENEWABLE OPERATING PERMIT

JULY 26, 2021 - STAFF REPORT

ROP Number

MI-ROP-B3610-2021

Purpose

Major stationary sources of air pollutants, and some non-major sources, are required to obtain and operate in compliance with an ROP pursuant to Title V of the federal Clean Air Act; and Michigan's Administrative Rules for Air Pollution Control promulgated under Section 5506(1) of Act 451. Sources subject to the ROP program are defined by criteria in Rule 211(1). The ROP is intended to simplify and clarify a stationary source's applicable requirements and compliance with them by consolidating all state and federal air quality requirements into one document.

This Staff Report, as required by Rule 214(1), sets forth the applicable requirements and factual basis for the draft ROP terms and conditions including citations of the underlying applicable requirements, an explanation of any equivalent requirements included in the draft ROP pursuant to Rule 212(5), and any determination made pursuant to Rule 213(6)(a)(ii) regarding requirements that are not applicable to the stationary source.

General Information

Stationary Source Mailing Address:	Pharmacia & Upjohn Company, LLC 7000 Portage Road Kalamazoo, Michigan 49001-0199
Source Registration Number (SRN):	B3610
North American Industry Classification System (NAICS) Code:	325412
Number of Stationary Source Sections:	3
Is Application for a Renewal or Initial Issuance?	Renewal
Application Number:	201800140
Responsible Official:	David Breen, Site Leader 269-833-0405
AQD Contact:	Monica Brothers, Environmental Quality Analyst 269-312-2535
Date Application Received:	November 7, 2018
Date Application Was Administratively Complete:	November 7, 2018
Is Application Shield in Effect?	Yes
Date Public Comment Begins:	July 26, 2021
Deadline for Public Comment:	August 25, 2021

Source Description

Pharmacia & Upjohn Company, LLC (Facility), a subsidiary of Pfizer Inc., operates a manufacturing complex in the city of Kalamazoo. The complex consists of many separate manufacturing buildings, pilot plant and laboratory operations, waste handling operations, storage tank farms, office or other support buildings, and a free-standing power plant building. The Facility is separated into three sections for permitting purposes. The engineering and maintenance division (Section 1) includes the power plant, miscellaneous fuel firing devices, and maintenance operations. The Drug Products (DP) is a division (Section 2) that includes equipment used to formulate finished products from active and other ingredients. This includes mixing, blending, drying, weighing, granulating, compressing, coating, filling, printing, and packaging equipment. The third division (Section 3) is referred to as Active Pharmaceutical Ingredients (API). This includes equipment used for raw material storage, biological fermentation, chemical synthesis, purification, separation, and drying. It also includes the tank farms for solvent and other liquid storage.

The facility is located about five miles SSE of downtown Kalamazoo, in both an industrial and residential area. Other industrial facilities are located north of the Pharmacia & Upjohn Company, LLC, but it is mostly residential to the southwest and west of the facility.

The following table lists stationary source emission information as reported to the Michigan Air Emissions Reporting System (MAERS) for the year **2020**.

TOTAL STATIONARY SOURCE EMISSIONS

Pollutant	Tons per Year
Carbon Monoxide (CO)	76.9
Lead (Pb)	0.017
Nitrogen Oxides (NO_x)	177.3
Particulate Matter (PM)	24.2
Sulfur Dioxide (SO_2)	180.7
Volatile Organic Compounds (VOCs)	23.1

The following table lists Hazardous Air Pollutant emissions as calculated for the year 2018 by the company:

Individual Hazardous Air Pollutants (HAPs) **	Tons per Year
Hydrogen Chloride (HCl)	14.00
Methylene Chloride (DCM)	0.44
Total Hazardous Air Pollutants (HAPs)	**14.44**

**As listed pursuant to Section 112(b) of the federal Clean Air Act.

See Parts C and D in the ROP for summary tables of all processes at the stationary source that are subject to process-specific emission limits or standards.

Regulatory Analysis

The following is a general description and history of the source. Any determinations of regulatory non-applicability for this source are explained below in the Non-Applicable Requirement part of the Staff Report and identified in Part E of the ROP.

The stationary source is in Kalamazoo County, which is currently designated by the United States Environmental Protection Agency (USEPA) as attainment/unclassified for all criteria pollutants.

The stationary source is subject to Title 40 of the Code of Federal Regulations (CFR) Part 70, because the potential to emit of carbon monoxide (CO), nitrogen oxides (NO_x), particulate matter (PM), sulfur dioxide (SO_2), and volatile organic compounds (VOC), exceeds 100 tons per year, and the potential to emit of any single HAP regulated by Section 112 of the federal Clean Air Act, is equal to or more than 10 tons per year and/or the potential to emit of all HAPs combined is equal to or more than 25 tons per year.

The stationary source is subject to review under the Prevention of Significant Deterioration regulations of 40 CFR 52.21 because at the time of New Source Review permitting the potential to emit of CO, NO_x, PM, SO_2, and VOC was greater than 100 tons per year, and the fossil fuel fired boilers at the stationary source have a combined heat input of greater than 250 million British Thermal Unit (MMBTU) per hour.

At this time, there are no GHG applicable requirements to include in the ROP. The mandatory GHG Reporting Rule under 40 CFR Part 98, is not an ROP applicable requirement and is not included in the ROP.

For Section 1 of the ROP, the source has added or modified equipment since the last ROP renewal that changed their criteria pollutant and HAPs PTE. New gas-fired boilers have been added through PTI Nos. 99-18, 57-15, and 49-20 which will be rolled-in during this renewal. These PTIs add three new gas-fired boilers and change the back-up fuel from propane to #2 fuel oil. Also, all five coal-fired boilers, (EUEBLR43-3-S1, EUEBLR43-4-S1, EUEBLR43-5-S1, EUEBLR43-6-S1, and EUEBLR43-1-S1) have now been dismantled. The associated ash handling system has also been rendered non-operational and has been removed from the ROP.

For Section 3 of the ROP, the source has added or modified equipment since the last ROP renewal that changed their criteria pollutant PTE. These changes are addressed in PTI Nos. 26-18, 1-19, 149-19, 21-19, 16-19A, 107-19, and 26-18A which will be rolled into the ROP during this renewal. PTI No. 26-18 adds a new rotoclone. PTI No. 149-19 makes modifications to a rotoclone. PTI No. 1-19 adds a new waste receiver tank. PTI No. 21-19 adds a new dust collector for particulate control in Building 335. This new dust collector replaces the existing DC-350 dust collector. PTI No. 16-19A is for a replacement rotoclone in Building 38. PTI No. 107-19 is for a new portable charge tank (ID# 173TANK1111-1) in EUCR3173-S3. PTI No. 26-18A is for two replacement acetone tanks (ID#TANK1022-1 and TANK1022-2). Emissions from the replacement tanks are controlled by the thermal oxidizer.

EUCR4172-S3 at the stationary source is subject to the Standards of Performance for storage tanks promulgated in 40 CFR Part 60, Subparts A and Kb.

EUBLR43-9-S1, EUEBLR43-10-S1, and EUEBLR43-11-S1 at the stationary source are subject to the Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units promulgated in 40 CFR Part 60, Subparts A and Db.

EURICE-CI-NSPS-S1 at the stationary source is subject to the Standards of Performance for Stationary Compression Ignition Reciprocating Internal Combustion Engines promulgated in 40 CFR Part 60, Subparts A and IIII. These units are also subject to 40 CFR Part 63, Subparts A and ZZZZ, but comply with these subparts by complying with the NSPS.

EURICE-SI-NSPS-S1 at the stationary source is subject to the Standards of Performance for Spark Ignition Reciprocating Internal Combustion Engines promulgated in 40 CFR Part 60, Subparts A and JJJJ. These units are also subject to 40 CFR Part 63, Subparts A and ZZZZ, but comply with these subparts by complying with the NSPS.

FGCFUG-S3 at the stationary source is subject to the National Emission Standard for Hazardous Air Pollutants for Equipment Leaks promulgated in 40 CFR Part 63, Subparts A, H, and I.

FGPHARMAMACT-S3 at the stationary source is subject to the National Emission Standard for Hazardous Air Pollutants for Pharmaceuticals Production promulgated in 40 CFR Part 63, Subparts A and GGG.

EUCR3173-S3 at the stationary source is subject to the National Emission Standard for Hazardous Air Pollutants for Pesticide Active Ingredient Production promulgated in 40 CFR Part 63, Subparts A and MMM. However, the source has elected to comply with 40 CFR Part 63, Subpart GGG, to demonstrate compliance based on 40 CFR 63.1360(h)(3).

EUEBLR43-7-S1, EUEBLR43-8-S1, and FGEBLR43-10&11-S1 at the stationary source are subject to the National Emission Standard for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters promulgated in 40 CFR Part 63, Subparts A and DDDDD.

EURICEMACT-S1 at the stationary source is subject to the National Emission Standard for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines promulgated in 40 CFR Part 63, Subparts A and ZZZZ.

EUB51GENERATOR-S1 at the stationary source is subject to the National Emission Standard for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines promulgated in 40 CFR Part 63, Subparts A and ZZZZ. However, according to 40 CFR 63.6590(b)(3)(iii), this engine has no requirements under this subpart.

The stationary source was not subject to R 336.1220 for Major Sources Impacting Nonattainment Areas at the time of New Source Review permitting.

The stationary source is not subject to 40 CFR Part 75 for the Acid Rain Program because the stationary source does not have an electric generating unit.

The AQD's Rules 287 and 290 were revised on December 20, 2016. FGRULE287(2)(c) and FGRULE290 are flexible group tables created for emission units subject to these rules. Emission units installed before December 20, 2016, can comply with the requirements of Rule 287 and Rule 290 in effect at the time of installation or modification as identified in the tables. However, emission units installed or modified on or after December 20, 2016, must comply with the requirements of the current rules as outlined in the tables.

The monitoring conditions contained in the ROP are necessary to demonstrate compliance with all applicable requirements and are consistent with the "Procedure for Evaluating Periodic Monitoring Submittals."

EUPKDRYPKGEQUIP-S2, EUPLSTERINJ-S2, EUSPECIALPKG-S2, EUC120R6ALL-S3, EUC38R6ALL-S3, EUC41MICKK33-S3, EUC41MICRONIZING-S3, EUC41MILLING-S3, EUC41NEOSPRAYDRYER-S3, EUC41NEOSTOR&HANDL-S3, EUC4335-S3, EUCR1127-S3, EUCR1155-S3, EUCR1166-S3, EUCR1195-S3 EUCR138-S3, EUCR2149-S3, EUCR244-S3, EUCR3173-S3, EUCR3207-S3, EUCR3225-S3, EUCR373-S3, EUCR466-S3, EUCR476-S3, and EUCR491COM-S3 do not have emission limitations or standards that are subject to the federal Compliance Assurance Monitoring rule pursuant to 40 CFR Part 64, because the unit(s) does/do not have potential pre-control emissions over the major source thresholds.

The emission limitations, a VOC limit of 37 tons per 12-month rolling time period, and a 21 pound per hour limit for toxic air contaminants other than methylene chloride and other VOC, from FGCRALLTOX-S3 at the stationary source are exempt from the federal Compliance Assurance Monitoring (CAM) regulation pursuant to 40 CFR 64.2(b)(1)(vi), because these limitations meet the CAM exemption for a continuous compliance determination method. A total organic carbon analyzer has been installed on the thermal oxidizer in conjunction with 40 CFR Part 63, Subpart GGG.

The thermal oxidizer in FGCRALLTOX-S3 has an HCl limit of 27 pounds per hour. This limit is not subject to CAM because the emission limit is not federally enforceable.

The emission limitations or standards for NOx from EUEBLR43-9-S1, EUEBLR43-10-S1 and EUEBLR43-11-S1 at the stationary source are exempt from the federal Compliance Assurance Monitoring (CAM) regulation pursuant to 40 CFR 64.2(b)(1)(vi), because these NOx limitations meet the CAM exemption for a continuous compliance determination method. These emission units are subject to 40 CFR Part 60, Subpart Db, which requires a continuous monitoring method for compliance.

Please refer to Parts B, C and D in the draft ROP for detailed regulatory citations for the stationary source. Part A contains regulatory citations for general conditions.

Source-Wide Permit to Install (PTI)

Rule 214a requires the issuance of a Source-Wide PTI within the ROP for conditions established pursuant to Rule 201. All terms and conditions that were initially established in a PTI are identified with a footnote designation in the integrated ROP/PTI document.

The following table lists all individual PTIs that were incorporated into previous ROPs. PTIs issued after the effective date of ROP No. MI-ROP-B3610-2014 are identified in Appendix 6 of the ROP.

PTI Number			
447-78	357-94	179-83	242-80
1209-91A	497-92	463-93	202-93
277-92A	837-92	923-92B	1106-92
105-93	1016-92	730-92A	207-93
132-94C	1351-91M	108-92I	424-92M
929-92J	227-02	55-03	137-03
137-03A	201-04	172-05	272-05
91-05	153-06	12-06A	106-07
20-08	21-08	68-08	297-08B
10-09	211-10	57-11	85-11
58-13	116-13	293-82	350-82
9-71	242-80B	127-91B	762-92
590-82	173-83	217-93	929-92I
854-92	1017-92	298-06	297-08
1016-92A	100-05	125-12A	166-89
298-08A	125-12		

Streamlined/Subsumed Requirements

This ROP does not include any streamlined/subsumed requirements pursuant to Rules 213(2) and 213(6).

Non-applicable Requirements

Part E of the ROP lists requirements that are not applicable to this source as determined by the AQD, if any were proposed in the ROP Application. These determinations are incorporated into the permit shield provision set forth in Part A (General Conditions 26 through 29) of the ROP pursuant to Rule 213(6)(a)(ii).

Processes in Application Not Identified in Draft ROP

The following table lists processes that were included in the ROP Application as exempt devices under Rule 212(4). These processes are not subject to any process-specific emission limits or standards in any applicable requirement.

PTI Exempt Emission Unit ID	Description of PTI Exempt Emission Unit	Rule 212(4) Citation	PTI Exemption Rule Citation
EUE-REFRIGERANT	Cold storage refrigerant equipment and storage of refrigerant	Rule 212(4)(a)	Rule 280(2)(a)
EUE-PORTHEATERS	Various natural gas-fired units used for space and service water heating	Rule 212(4)(c)	Rule 282(2)(b)(i)
EUE-LPGTANKS-S1	LPG storage tanks with capacity of ≤500 gallons	Rule 212(4)(d)	Rule 284(2)(b)
EUE-GASTANKS-S1	Gasoline dispensing facility with a tank capacity of ≤10,000 gallons	Rule 212(4)(d)	Rule 284(2)(g)(ii)
EUE-TORCHES-S1	Portable torch-cutting equipment	Rule 212(4)(e)	Rule 285(2)(j)

Draft ROP Terms/Conditions Not Agreed to by Applicant

This draft ROP does not contain any terms and/or conditions that the AQD and the applicant did not agree upon pursuant to Rule 214(2).

Compliance Status

The AQD finds that the stationary source is expected to be in compliance with all applicable requirements as of the effective date of this ROP.

Action taken by EGLE, AQD

The AQD proposes to approve this ROP. A final decision on the ROP will not be made until the public and affected states have had an opportunity to comment on the AQD's proposed action and draft permit. In addition, the USEPA is allowed up to 45 days to review the draft ROP and related material. The AQD is not required to accept recommendations that are not based on applicable requirements. The delegated decision maker for the AQD is Rex Lane, Kalamazoo District Supervisor. The final determination for ROP approval/disapproval will be based on the contents of the ROP Application, a judgment that the stationary source will be able to comply with applicable emission limits and other terms and conditions, and resolution of any objections by the USEPA.

State Registration Number	RENEWABLE OPERATING PERMIT	ROP Number
B3610	AUGUST 27, 2021 - STAFF REPORT ADDENDUM	MI-ROP-B3610-2021

Purpose

A Staff Report dated July 26, 2021, was developed to set forth the applicable requirements and factual basis for the draft Renewable Operating Permit (ROP) terms and conditions as required by Rule 214(1) of the administrative rules promulgated under Act 451. The purpose of this Staff Report Addendum is to summarize any significant comments received on the draft ROP during the 30-day public comment period as described in Rule 214(3). In addition, this addendum describes any changes to the draft ROP resulting from these pertinent comments.

General Information

Responsible Official:	David Breen, Site Leader 269-833-0405
AQD Contact:	Monica Brothers, Senior Environmental Quality Analyst 269-312-2535

Summary of Pertinent Comments

No pertinent comments were received during the 30-day public comment period.

Changes to the July 26, 2021 Draft ROP

No changes were made to the draft ROP.

State Registration Number: B3610

RENEWABLE OPERATING PERMIT

ROP Number: MI-ROP-B3610-2021a

MARCH 21, 2022 - STAFF REPORT FOR RULE 216(2) MINOR MODIFICATION

Purpose

On October 18, 2021, the Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD), approved and issued Renewable Operating Permit (ROP) No. MI-ROP-B3610-2021 to Pharmacia & Upjohn Company, LLC pursuant to Rule 214 of the administrative rules promulgated under Act 451. Once issued, a company is required to submit an application for changes to the ROP as described in Rule 216. The purpose of this Staff Report is to describe the changes that were made to the ROP pursuant to Rule 216(2).

General Information

Responsible Official:	David Breen, Site Leader 269-833-0405
AQD Contact:	Caryn E. Owens, Senior Environmental Engineer 231-878-6688
Application Numbers:	202100113, 202100150, 202200029, and 202200030
Date Applications for Minor Modifications were Submitted:	July 15, 2021, August 27, 2021, and January 31, 2022

Regulatory Analysis

The AQD has determined that the change requested by the stationary source meets the qualifications for a Minor Modification pursuant to Rule 216(2).

Description of Changes to the ROP

Minor Modification Number 202100113 was to incorporate PTI No. 30-21, which is for an additional slurry charge tank in Building 173 (under EUCR3173-S3). Emissions from this process tank are controlled by an existing thermal oxidizer (FGCRALLTOX-S3). The process tank will primarily be a source of PVOCs, TACs, and HAPs. The PTI was not required to go through the public participation process.

Minor Modification Number 202100150 was to incorporate PTI No. 37-21, which is to relocate existing equipment from Building 225 to Building 91, and add new equipment to Building 91, to allow the B91 9CPT process to continue operating. Some of the equipment the 9CPT process requires in Building 225 is currently supporting COVID-19 activities. Relocating the process, with new equipment in support, will allow 9CPT production to continue without interfering with the COVID activities. The PTI was not required to go through the public participation process.

Minor Modification Number 202200029 was to incorporate PTI No. 66-21, which is for a new HPLC system in EUCR3225-S3 in Building 225 (B225), which will be used to concentrate crude products run on the current chromatography columns in B225.

The new HPLC system will have new tanks installed to support the process and there will be a HPLC controller that will determine the solvent feed rates into the HPLC column. The column will separate products from solvents and impurities. A falling film evaporator may not be installed at the time of start-up but is planned to be installed in the future.

There will be a silica slurry that will be mixed with isopropyl alcohol (IPA); the IPA will be emitted uncontrolled through the silica slurry exhaust hood. The silica emitted through the silica slurry exhaust hood will be controlled by particulate control device scrubber SCRB1006, which is permitted to emit silica and will not be modified. Original emission calculations were based on the SCRB1006 total exhaust flow rate, rather than the process emissions, so there will be no increase in potential emissions from SCRB1006 as a result of the project.

Except for the silica slurry exhaust hood, emissions from the new equipment, including the tanks, will exhaust through FGCALLTOX-S3; no changes to the FGCALLTOX-S3 emission limits are proposed. The PTI was not required to go through the public participation process.

Minor Modification Number 202200030 was to incorporate PTI No. 116-21, which is for the operation of two portable tanks (TANK3650 and TANK3660) in two existing emission units (EUCR3225-S3 and EUCR491COM-S3). The tanks will be used in support of the production of lipids for processes that occur in other buildings. Both tanks will be located in either Building 91 or Building 225, depending on the operational needs of each building, where process emissions will be emitted through vents in either building. Both tanks will be cleaned in either building and emissions from cleaning, which can also occur in either building, will be vented to FGCRALLTOX-S3. The PTI was not required to go through the public participation process.

Compliance Status

The AQD finds that the stationary source is expected to be in compliance with all applicable requirements as of the effective date of this ROP.

Action Taken by EGLE

The AQD proposes to approve a Minor Modification to ROP No. MI-ROP-B3610-2021, as requested by the stationary source. A final decision on the Minor Modification to the ROP will not be made until any affected states and the United States Environmental Protection Agency (USEPA) has been allowed 45 days to review the proposed changes to the ROP. The delegated decision maker for the AQD is the District Supervisor. The final determination for approval of the Minor Modification will be based on the contents of the permit application, a judgment that the stationary source will be able to comply with applicable emission limits and other requirements, and resolution of any objections by any affected states or the USEPA.