

Application Type Renewal
Facility Type Industrial
Major / Minor Major

**NPDES PERMIT FACT SHEET
ADDENDUM 01**

Application No. PA0008419
APS ID 1035595
Authorization ID 1348598

Applicant and Facility Information

Applicant Name	<u>Cherokee Pharmaceuticals, LLC</u>	Facility Name	<u>Cherokee Pharmaceuticals</u>
Applicant Address	<u>100 Avenue C, P.O. Box 367 Riverside, PA 17868-0367</u>	Facility Address	<u>100 Avenue C, P.O. Box 367 Riverside, PA 17868</u>
Applicant Contact	<u>Adam Wojtowicz</u>	Facility Contact	<u>Adam Wojtowicz</u>
Applicant Phone	<u>570-271-2045</u>	Facility Phone	<u>570-271-2045</u>
Client ID	<u>259313</u>	Site ID	<u>249423</u>
SIC Code	<u>2833, 2834</u>	Municipality	<u>Riverside Borough</u>
SIC Description	<u>See Narrative</u>	County	<u>Northumberland</u>
Date Published in PA Bulletin	<u>November 04, 2023</u>	EPA Waived?	<u>No</u>
Comment Period End Date	<u>December 19, 2023</u>	If No, Reason	<u>Major IW Facility, Significant CB Discharge</u>
Purpose of Application	<u>Application for a renewal of an NPDES permit for discharge of treated Industrial</u>		

Internal Review and Recommendations

INTRODUCTION

Cherokee Pharmaceuticals, LLC (Cherokee) has applied to renew its NPDES permit authorizing the treated industrial wastewater and stormwater discharge from the Riverside, PA Cherokee manufacturing facility.

APPLICATION

Cherokee submitted the *NPDES Application for Individual Permit to Discharge Industrial Wastewater* (DEP #3800-PM-BCW0008b). This application was received by the Department via File Transfer Protocol (FTP) on April 02, 2021 and considered administratively complete on April 20, 2021. Adam T. Wojtowicz, Senior Safety & Environmental Specialist, is both the client and site contact for Cherokee. His additional contact information is (fax) 570-271-4135 and (email) adam.wojtowicz@merck.com. An additional Cherokee contact is Phillip Bahner, Safety and Environmental Specialist. His contact information is (phone) 570-271-2116 and (email) phillip.bahner@merck.com.

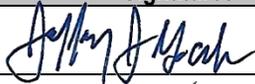
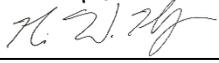
DRAFT PERMIT

A draft permit was prepared in early October 2023 and emailed to the permittee on October 18, 2023.

PUBLIC PARTICIPATION

The draft permit was published in the PA Bulletin on November 04, 2023 (Volume 53, Number 44, Page 6880).

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Approve	Deny	Signatures		Date
X		Jeffrey J. Gocek, EIT	 Project Manager	02/02/2024
X		Nicholas W. Hartranft, PE	 Environmental Engineer Manager	02/02/2024
X		Thomas M. Randis	 Environmental Program Manager	02/02/2024

Internal Review and RecommendationsFACILITY BACKGROUND

Cherokee, a division of Merck Sharp and Dohme Corporation, is a pharmaceutical manufacturing plant located in Riverside, PA across the Susquehanna River from Danville. The site consists of 323 acres, 127 of which are inside the fence line. The site contains approximately 100 buildings and employs approximately 340 employees. From 1965 to 2007, Merck and Co., Inc. (Merck) owned and operated the Riverside manufacturing facility. In 2008 Merck sold this facility to Cherokee and in 2010 re-acquired the facility from Cherokee. This plant makes pharmaceutical active ingredients using chemical synthesis processes. The chemical synthesis process products are Cilastatin, Ertapenem and Imipenem.

Cherokee listed SIC codes of 2833 and 2834 on the application. According to <http://www.osha.gov>, SIC 2833 is *Medicinal Chemicals and Botanical Products*; defined as "Establishments primarily engaged in (1) manufacturing bulk organic and inorganic medicinal chemicals and their derivatives and (2) processing (grading, grinding, and milling) bulk botanical drugs and herbs. Included in this industry are establishments primarily engaged in manufacturing agar-agar and similar products of natural origin, endocrine products, manufacturing or isolating basic vitamins, and isolating active medicinal principals such as alkaloids from botanical drugs and herbs." SIC 2834 is *Pharmaceutical Preparations*; defined as "Establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The greater part of the products of these establishments are finished in the form intended for final consumption, such as ampoules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions. Products of this industry consist of two important lines, namely: (1) pharmaceutical preparations promoted primarily to the dental, medical, or veterinary professions, and (2) pharmaceutical preparations promoted primarily to the public."

SITE CLOSURE

An announcement was made by Cherokee in May 2022 informing the public that production at the Riverside facility would cease in 2024. The discontinuation of the active pharmaceutical ingredient manufacturing will lead to the ultimate closure of the facility. Cherokee plans to close the facility in a phased approach over several years. The decommissioning of the facility, along with the Industrial Wastewater Treatment Facility, is projected to occur during 2025 and 2026.

DRAFT PERMIT COMMENTSCherokee

Cherokee's draft permit comments were provided to the Department in a letter dated December 11, 2023 from Daniel Morris, Director of Safety and Environmental. The comments are summarized below.

1. *Cooling Water Intake Systems*

Following a re-evaluation of the cooling water system, Cherokee has determined that water withdrawal for cooling purposes is below the regulatory threshold of 25% (annual basis), and will drop below the 25% threshold based on a 5-year actual intake flow basis (as defined in 40 CFR § 125.91) following the end of manufacturing. The need for the withdrawal of cooling water will cease near the end of 2028.

Based on this information, Cherokee has requested the removal of the Part C condition (VII) requiring a site-specific entrainment study. Cherokee has also requested the language from the Part C condition (VI) for cooling water intake structures be amended to reflect the planned removal of the cooling water systems.

2. *Outfall 101 Mass and Concentration Limits*

Cherokee requested the Department use the 95th percentile flow (0.77 MGD) for the calculation of mass-based effluent limit guideline (ELG) instead of the long-term average (LTA) flow (0.59 MGD). The Fact Sheet described using 0.77 MGD but incorrectly calculated the mass limitations using 0.59 MGD.

3. *Toxics Screening Analysis*

The Fact Sheet described eight pollutants identified during the use of the Department's Toxics Management Spreadsheet (TMS), due to non-detect values greater than those of the Target Quantitation Limits (TQLs). Cherokee re-sampled those parameters and all but one had non-detect results less than the TQLs. Cherokee requested that limitations be removed for those seven non-detect parameters and that the remaining parameter (n-Nitrosodi-n-Propylamine) be monitored only once per year.

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4. Stormwater Annual Report

Page 34 of the NPDES permit references the submission of a Stormwater Annual Report, using a Department form. No form was provided. Cherokee requested the form.

5. Part A Ammonia Nitrogen

Monitoring requirements at Outfall 001 for Ammonia-Nitrogen were included in Part A.I.A and Part A.I.F. Cherokee requested that this parameter be listed and reported in one location in the permit only.

Environmental Protection Agency

In an email dated November 14, 2023, staff from the Environmental Protection Agency (EPA) acknowledged earlier receipt of the draft permit and informed the Department that EPA had chosen to only perform a limited review of the draft permit based on the wasteload allocation assumptions and requirements of the Chesapeake Bay Total Maximum Daily Load (TMDL), cooling water intake structure (CWIS) and effluent limit guidelines (ELGs) for Pharmaceutical Manufacturing set forth in the federal regulations. No comments were provided.

Public

No comments were received from the public.

COMMENT RESOLUTION

Cherokee

1. Cooling Water Intake Systems

Based on Cherokee's reevaluation of the CWIS for future use, which indicates that the water currently withdrawn exclusively for cooling (22.1%) is less than the 25% use threshold as described in 40 CFR § 125.91. Cherokee plans to no longer need cooling water by the end of 2028 and has plans to decommission the cooling towers once manufacturing has ceased or shortly thereafter. Cherokee also reiterated that the existing closed-cycle recirculation system currently qualifies as Best Technology Available (BTA) for both entrainment and impingement, in accordance with 40 CFR § 125.92(c), 40 CFR § 125.94(c)(1) and 40 CFR 125.94(d). Furthermore, Cherokee does not meet the 2.0 million gallons per day (MGD) cumulative design intake flow (DIF) as described in 40 CFR § 125.91(a)(2) for existing facilities to be subject to the CWIS requirements (40 CFR §§ 125.94 through 125.99).

The Department has decided to remove the Site-Specific Entrainment Study requirement from the draft permit (Part C VII) and replace it with a compliance schedule which will require the cessation of the cooling water intake by December 31, 2028.

2. Outfall 101 Mass and Concentration Limits

At Cherokee's request, the Department has recalculated the effluent limitations using the 95th percentile flow of 0.77 MGD.

3. Toxics Screening Analysis

Based on the sampling results submitted with the draft permit comments, the following parameters have been removed from the draft permit; Benzo(a)Anthracene, Benzo(a)Pyrene, 3,4-Benzofluoranthene, Dibenzo(a,h)Anthracene, Hexachlorobenzene, Indeno(1,2,3-cd)Pyrene, and n-Nitrosodimethylamine. Only n-Nitrosodi-n-Propylamine remains in the permit with a monitoring requirement. The Department has agreed to reduce the monitoring frequency to once per year, in accordance with the other annual non-use screening parameters in the permit.

4. Stormwater Annual Report

The NPDES Discharges of Stormwater Associated with Industrial Activity Annual Report form (DEP #3850-PM-BCW0083) will be included with the draft permit.

5. Part A Ammonia Nitrogen

The requirement to monitor Ammonia-Nitrogen in Part A.I.A was a typographical error and has been removed as requested by Cherokee.

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NEW DRAFT PERMIT REQUIRED

Because of the new compliance schedule and removal of certain effluent limitations, the Department will redraft this permit.

Any portions of the Fact Sheet and draft permit not discussed in this Fact Sheet Addendum remain in effect.

ADDITIONAL CONSIDERATIONS

Special Permit Conditions (Part C)

- Chesapeake Bay
- Industrial Stormwater Requirements
- Whole Effluent Toxicity – No Permit Limits
- Chemical Additives
- Chlorine Minimization
- Cooling Water Intake Structures
- Compliance Schedule

Supplemental DMRs

- Daily Monitoring
- Non-Compliance
- Lab Accreditation
- Chemical Additives
- Whole Effluent Toxicity
- Stormwater Annual Inspection

PROPOSED EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

The limitations and monitoring requirements specified below are proposed for the draft permit and reflect the most stringent limitations amongst technology, water quality and BPJ.

Outfall 001, Effective Period: Permit Effective Date through Permit Expiration Date

Discharge Parameter	Mass Limits (lb/day)		Concentrations (mg/L unless noted)				Monitoring Requirements	
	Monthly Average	Daily Maximum	Minimum	Monthly Average	Daily Maximum	IMAX	Minimum Measurement Frequency	Required Sample Type
Flow (MGD)	Report	Report					Continuous	Meter
pH			6.0			9.0	1/Day	Grab
Oil & Grease				15		30	1/Week	Grab
Dissolved Iron						7.0	1/Week	Grab
Total Suspended Solids					Report		1/6 Months	Grab
Chemical Oxygen Demand					Report		1/6 Months	Grab
Total Aluminum		Report			Report		1/Year	Grab
Total Iron		Report			Report		1/Year	Grab
Total Mercury		Report			Report		1/Year	Grab
Total PCBs		Report			Report		1/Year	Grab

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Outfall 101, Effective Period: Permit Effective Date through Permit Expiration Date

Discharge Parameter	Mass Limits (lb/day)		Concentrations (mg/L unless noted)				Monitoring Requirements	
	Monthly Average	Daily Maximum	Minimum	Monthly Average	Daily Maximum	IMAX	Minimum Measurement Frequency	Required Sample Type
Flow (MGD)	Report	Report					Continuous	Meter
pH			6.0 Inst Min			9.0	1/Day	Grab
BOD ₅	890	Report		Report	Report	275	1/Week	24 Hour Composite
TSS	1,510	Report		Report	Report	470	1/Week	24 Hour Composite
COD	3,275	Report		510	Report	1020	1/Week	24 Hour Composite
Ammonia-N	185	540		29.0	84.0	105	1/Week	24 Hour Composite
Acetone	1.28	3.21		0.20	0.50	0.62	2/Month	24 Hour Composite
n-Butyl Acetate	3.21	8.34		0.50	1.30	1.62	2/Month	24 Hour Composite
Ethyl Acetate	3.21	8.34		0.50	1.30	1.62	2/Month	24 Hour Composite
Isopropyl Acetate	3.21	8.34		0.50	1.30	1.62	2/Month	24 Hour Composite
Methyl Formate	3.21	8.34		0.50	1.30	1.62	2/Month	24 Hour Composite
Ethanol	26.32	64.21		4.10	10.00	12.50	2/Month	24 Hour Composite
Isopropanol	10.27	25.04		1.60	3.90	4.87	2/Month	24 Hour Composite
Methanol	26.32	64.21		4.10	10.00	12.50	2/Month	24 Hour Composite
Dimethyl Sulfoxide	240.81	587.59		37.50	91.50	114.30	2/Month	24 Hour Composite
Triethyl Amine	655.02	1605.45		102.00	250.00	312.50	2/Month	24 Hour Composite
Phenol	0.12	0.32		0.02	0.05	0.06	2/Month	24 Hour Composite
Benzene	0.12	0.32		0.02	0.05	0.06	2/Month	24 Hour Composite
Toluene	0.12	0.38		0.02	0.06	0.07	2/Month	24 Hour Composite
n-Hexane	0.12	0.19		0.02	0.03	0.05	2/Month	24 Hour Composite
n-Heptane	0.12	0.32		0.02	0.05	0.06	2/Month	24 Hour Composite
Methylene Chloride	1.92	5.77		0.30	0.90	1.12	2/Month	24 Hour Composite
Chloroform	0.83	1.28		0.13	0.20	0.32	2/Month	24 Hour Composite
1,2-Dichloroethane	0.64	2.56		0.10	0.40	0.50	2/Month	24 Hour Composite
Tetrahydrofuran	16.69	53.94		2.60	8.40	10.50	2/Month	24 Hour Composite
Acetonitrile	65.50	160.54		10.20	25.00	31.25	2/Month	24 Hour Composite
Cyanide		Report			Report		1/Year	24 Hour Composite
4-Methyl-2-Pentanone		Report			Report		1/Year	24 Hour Composite
Isobutyraldehyde		Report			Report		1/Year	24 Hour Composite
n-Amyl Acetate		Report			Report		1/Year	24 Hour Composite
Amyl Alcohol		Report			Report		1/Year	24 Hour Composite
Methyl Cellosolve		Report			Report		1/Year	24 Hour Composite
Xylenes		Report			Report		1/Year	24 Hour Composite
Chlorobenzene		Report			Report		1/Year	24 Hour Composite
o-Dichlorobenzene		Report			Report		1/Year	24 Hour Composite
Isopropyl Ether		Report			Report		1/Year	24 Hour Composite
Diethyl Amine		Report			Report		1/Year	24 Hour Composite
n-Nitrosodi-n-Propylamine		Report			Report		1/Year	24 Hour Composite
BOD ₅ Raw Influent	Report	Report		Report	Report		1/Week	24 Hour Composite
COD Raw Influent	Report	Report		Report	Report		1/Week	24 Hour Composite

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Outfall 201, Effective Period: Permit Effective Date through Permit Expiration Date

Discharge Parameter	Mass Limits (lb/day)		Concentrations (mg/L unless noted)				Monitoring Requirements	
	Monthly Average	Daily Maximum	Minimum	Monthly Average	Daily Maximum	IMAX	Minimum Measurement Frequency	Required Sample Type
Flow (MGD)	Report	Report					1/Week	Estimate
Total Suspended Solids				30			1/Month	Grab
Total Iron				2.0			1/Month	Grab
Total Aluminum				4.0			1/Month	Grab
Total Manganese				1.0			1/Month	Grab

Outfalls 002 & 003, Effective Period: Permit Effective Date through Permit Expiration Date

Discharge Parameter	Mass Limits (lb/day)		Concentrations (mg/L unless noted)				Monitoring Requirements	
	Monthly Average	Daily Maximum	Minimum	Monthly Average	Daily Maximum	IMAX	Minimum Measurement Frequency	Required Sample Type
Total Nitrogen					Report		1/6 Months	Grab
Total Phosphorus					Report		1/6 Months	Grab
Total Suspended Solids					Report		1/6 Months	Grab
Oil and Grease					Report		1/6 Months	Grab
pH					Report		1/6 Months	Grab
Chemical Oxygen Demand					Report		1/6 Months	Grab

Outfall 001, Effective Period: Permit Effective Date through Permit Expiration Date

Discharge Parameter	Mass Load (lb)		Concentrations (mg/L)			Monitoring Requirements	
	Monthly	Annual	Minimum	Monthly Average	Maximum	Minimum Measurement Frequency	Required Sample Type
Ammonia-N	Report	Report		Report		2/Week	24 Hour Composite
Kjeldahl-N	Report			Report		2/Week	24 Hour Composite
Nitrate-Nitrite as N	Report			Report		2/Week	24 Hour Composite
Total Nitrogen	Report	Report		Report		1/Month	Calculation
Total Phosphorus	Report	Report		Report		2/Week	24 Hour Composite
Net Total Nitrogen	Report	64,884				1/Month	Calculation
Net Total Phosphorus	Report	11,748				1/Month	Calculation

END of Fact Sheet