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MAR 15 2010

**CHEROKEE**  
**PHARMACEUTICALS**  
A PRWT LIFE SCIENCES COMPANY

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DEPARTMENT OF  
 ENVIRONMENTAL PROTECTION

RECEIVED

March 11, 2010

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MAR 15 2010

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Environmental Quality Board  
 PO Box 8477  
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ENVIRONMENTAL QUALITY BOARD

Re: Revisions to 25 Pa. Code Chapter 92 – NPDES Program  
 Comments on Draft Regulation  
 Cherokee Pharmaceuticals, LLC

RECEIVED  
 MAR 17 2010  
 INDEPENDENT REGULATORY  
 REVIEW COMMISSION

Dear John Hanger, Environmental Quality Board Chairman:

Cherokee Pharmaceuticals, LLC is a bulk chemical manufacturing site which produces active pharmaceutical ingredients for a number of human and animal health products. The site also has the capability to produce a broad range of specialty chemical and fermentation products. The facility is located in the Borough of Riverside, across the Susquehanna River from Danville.

Currently, the site employs approximately 425 full-time employees. Cherokee Pharmaceuticals, LLC is a Minority Owned Business Enterprise and is a wholly owned subsidiary of PRWT Services, Inc. of Philadelphia.

The Department has specifically requested industry input regarding the technology based standards proposed under 25 Pa. Code Chapter 92a.48. Per this request, Cherokee Pharmaceuticals, LLC is submitting the following comments:

- 1) In developing the revisions to Chapter 92, the Department has chosen to take a "one size fits all" approach for regulating conventional pollutants from industrial point source discharges. Industrial point sources vary widely and a "one size fits all" approach is not applicable.

25 Pa. Code §92a.48(a)(4) states that:

***"For facilities discharging conventional pollutants in industrial waste, the monthly average discharge limitation for BOD<sub>5</sub> and TSS may not exceed 60 milligrams per liter. If CBOD<sub>5</sub> is specified instead of BOD<sub>5</sub>, the limitation may not exceed 50 milligrams per liter."***

Wastewater discharges from industrial point sources are currently regulated under industry specific federal Effluent Limitations Guidelines (ELG's) promulgated by EPA. In the ELG development process, EPA individually evaluated each point source discharge category to determine applicable ELG's. Under 33 U.S.C.A. §§ 1316, ELG's are developed as:

***"standards for the control of the discharge of pollutants which reflect the greatest degree of effluent reduction which the Administrator determines to be achievable through the application of the best available demonstrated control technology, processes, operating methods, or other alternatives, including, where practicable, a standard permitting no discharge of pollutants"***

Influent loading strengths vary drastically from industrial point source to industrial point source. EPA has recognized this wide variation in influent loading strength and taken an industry specific approach to determine the best available technology that is economically achievable for each point source category. EPA has chosen to develop industry specific effluent guidelines because they recognize that a "one size fits all" approach is not applicable to industrial point sources.

For example, per EPA's Pharmaceutical ELG development document (EPA 821-R-95-019), influent concentrations of BOD<sub>5</sub> and TSS to pharmaceutical wastewater treatment plants are as follows:

- BOD<sub>5</sub> – Mean of 1975 mg/L for direct dischargers
- TSS – Mean of 963 mg/L for direct dischargers

As a comparison, influent concentrations of BOD<sub>5</sub> and TSS to municipal wastewater treatment plants are as follows:

- BOD<sub>5</sub> – Average of 220 mg/L
- TSS – Average of 220 mg/L

As can be seen above, pharmaceutical wastewaters have significantly higher concentrations of conventional pollutants than average municipal wastewaters. Assuming the above mean influent concentrations for pharmaceutical wastewaters, achieving effluent concentrations of 60 mg/L for BOD<sub>5</sub> and TSS would represent the following reductions via treatment:

- BOD<sub>5</sub> – 97% reduction
- TSS – 94% reduction

The Pharmaceutical Effluent Limitation Guidelines (40 CFR § 439) require a 90% removal efficiency for BOD<sub>5</sub> (with 1.6 multiplier for TSS). This removal efficiency is already greater than the 85% removal that is required by the secondary treatment regulation (40 CFR §133.102) for municipal wastewater treatment plants.

We ask that the Department reconsider the effluent limits proposed under 25 Pa. Code Chapter 92a.48 as the Department has not considered the variability industrial wastewaters and the degree of treatment required to meet the proposed limitations. EPA has individually evaluated each point source category, and individually determined effluent limits which reflect the greatest degree of effluent reduction that is achievable.

The Department has not presented any scientific or technological basis for proposing limits more stringent than EPA's ELG's. If the Department believes that additional technology based standards are necessary for conventional pollutants, we ask that a case-by-case evaluation be conducted of each industrial point source category to

determine reasonable level of treatment for each point source category based on the characteristics of the wastewater being treated.

- 2) In the preamble to the Proposed Rulemaking (40 Pa. B. 847) the Department states (§92a.48 Industrial Waste Permit):

***"A new proposed revision would require that industrial discharges of conventional pollutants be assigned technology-based limits of no greater than 50 mg/L CBOD<sub>5</sub> and 60 mg/L TSS. This provision is intended to address situations where the application of certain outdated technology-based requirements for industrial sources may result in inappropriately permissive technology-based effluent limits. For industrial sources, the Federal Effluent Limitation Guideline (ELG) often is the applicable technology-based requirement. In some cases, the Federal ELG is based on units of mass pollutant per unit of production, such that a production operation might be assigned a permissible number of pounds of CBOD<sub>5</sub> that may be discharged per unit of production. When converted into concentration units, the effluent limits may be inappropriately permissive."***

Although some ELG's are defined on a mass per unit of production basis, that is not the case for all Industrial Point source categories. In the case of the pharmaceutical point source category, effluent limitations for BOD<sub>5</sub> and TSS are specified based on 90% removal of BOD<sub>5</sub> from the treatment plant influent. Effluent limitations are not permissively high as they are based on treatment efficiencies greater than the requirement of the secondary treatment regulation.

The Department is making generalizations that are not valid for all industrial point source categories. The Clean Streams Law (35 P.S. 691.5(a)(1)) requires the Department to consider water quality management in the "watershed as a whole." Based on this pharmaceutical industry example, we do not believe the Department has not considered all industrial point source categories in the watershed fairly based on their ability to control BOD<sub>5</sub>.

As was stated above, the Department has not presented any scientific or technological basis why it is believed that EPA's ELG's are obsolete.

- 3) In the preamble to the Proposed Rulemaking (40 Pa. B. 847) the Department states that compliance costs for most facilities are limited to the revised application and annual fees.

Again, the Department is making generalizations based on limited information about industrial wastewater treatment facilities. Per the Department's technical guidance for Industrial Wastewater Management (DEPID 362-0300-004) wastewater treatment requirements are determined for industrial facilities based on technology based effluent limits as defined by EPA's ELG's under Section 301 of the Federal Clean Water Act. Thus, the basis of design for industrial wastewater treatment facilities is meeting EPA's effluent limitation guidelines. The Department has reviewed and approved these designs as part of the water quality management permitting process.

Facilities with ELG's that are higher than the proposed limitations under §92a.48 will be required to upgrade treatment facilities to continually meet proposed effluent limits as these facilities are not currently designed to achieve these limitations.

Cherokee Pharmaceuticals wastewater treatment facility is designed to meet the effluent limitations imposed by EPA's ELG's. We estimate that to comply with the proposed changes to Chapter 92, we would be required to install additional aeration and settling capacity. Our engineering firm has estimated this to be a multi-million dollar project, possibly approaching 10 million dollars. The Clean Streams Law (35 P.S. 691.5(a)(5)) requires the Department to consider the immediate and long range economic impacts of this proposed regulation. Because the Department states that the compliance costs for this regulation will be limited to increased fees, it is evident that the Department has not fully considered the economic impacts of this regulation as required by the Clean Streams Law.

- 4) The Department already has mechanisms in place to protect the water quality of receiving water bodies via Chapter 93. Department water quality engineers model each discharge with the WQM 7.0 model to determine if additional water quality based effluent limitations for BOD<sub>5</sub> are required to protect water quality during each permit renewal cycle. If effluent limits are justified to prevent in-stream water quality violations, they are applied at the discharge point. This modeling method has proven very effective in protecting in-stream water quality across the Commonwealth.

If the basis of promulgating additional technology based effluent limits for industrial dischargers is violation of water quality standards on receiving water bodies, the Department needs to re-evaluate the dischargers that are causing water quality violations instead of blanketing all industrial point source categories with an unjustified technology based standard. The mechanisms are already in place under Chapter 93 to prevent in-stream water quality violations.

- 5) The secondary treatment regulation includes provisions such that POTW's that receive high strength wastewaters from industries are granted increased effluent limits for conventional pollutants based on the ELG for the industry that discharges high strength wastewater to the POTW.

In development of the secondary treatment regulation, EPA has acknowledged that it is not technically feasible for POTW's to treat industrial wastewaters to greater levels than the ELG's.

The Department also recognizes this in the Technical Guidance for the Development and Specification of Effluent Limitations in NPDES Permits (DEPID 362-0400-001) where guidance is give to increase effluent limits of POTW's who receive high strength industrial wastewaters. The increase in effluent concentration granted is directly proportional to the ELG and flow of the industrial contributor.

By granting this increase in effluent concentration, the Department recognizes that treatment above and beyond the ELG is not feasible for POTW's using biological treatment processes. Many industrial dischargers utilize biological treatment process to treat wastewater. These processes are very similar in design to municipal wastewater treatment plants, and the feasibility of treating wastewaters to lower concentrations is the same.

Again, as was stated above, the industrial ELG's are the best available technology that represents the greatest degree of effluent reduction achievable for each industrial point source category. The Department has not presented any technological or scientific basis as to why it is believed that the proposed standards for conventional pollutants are even achievable for industrial dischargers. If the

Department chooses to implement additional technology based standards for conventional pollutants for industrial dischargers, a case-by case- evaluation should to be conducted for each point source category.

- 6) In the preamble to the Proposed Rulemaking (40 Pa. B. 847), the Department states that "the great majority" of industrial dischargers already meet the additional standards that are proposed for industrial dischargers of conventional pollutants. Because of this, the Department states that the "requirement will affect few industrial facilities."

While a quick look at Discharge Monitoring Reports may lead the Department to believe that few industrial facilities will be affected, it is not necessarily the case. The true test of this statement is based on the design of the industrial wastewater treatment plant.


Industrial wastewater treatment plants are designed to meet EPA's ELG's. Many ELG's are higher than the Department's proposed limitations, thus industrial wastewater treatment plants are not designed to meet the proposed limitations for conventional pollutants. On the surface, it may appear that facilities are capable of meeting these limitations because they are not currently operating at design flow and/or loading conditions due to the economic conditions throughout the Commonwealth.

As the economy improves, and industries take on new business opportunities, wastewater flows and loadings have the potential to increase back to design conditions. At design loading conditions, facilities where the governing ELG is higher than the proposed limitations will not be able to comply with the proposed limitations without making upgrades to their treatment facilities.

By implementing the proposed standards for conventional pollutants for industrial dischargers, the Department will have a negative impact on the growth of business in the Commonwealth.

Thank you for your consideration in this matter. We look forward to working with the Department to address the regulation in a manner that is protective of both the environment and the Commonwealth's industry.

Sincerely,



Brant Zell

Cc: Northumberland County Commissioners  
Montour County Commissioners  
Representative Merle Phillips  
Senator John Gordner  
Senator Mary Jo White  
Senator Ray Musto  
Representative Scott Hutchinson  
Representative Camille George