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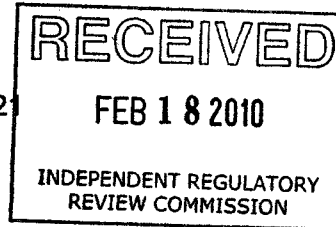
ENVIRONMENTAL QUALITY BOARD

CHEROKEE
PHARMACEUTICALS
A PRWT LIFE SCIENCES COMPANY

February 5, 2010

CERTIFIED MAIL: 7007 0220 0004 3467 3621

Environmental Quality Board
PO Box 8477
Harrisburg, PA 17150-8477



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Riverside, PA 17868
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Re: Revisions to 25 Pa. Code Chapter 95 – Wastewater Treatment Requirements
Comments on Draft Regulation
Cherokee Pharmaceuticals, LLC

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 revisions to 25 Pa. Code Chapter 95, as proposed, have the potential to limit the future growth of our business as well as negatively impact the viability of our current business. As such, Cherokee Pharmaceuticals, LLC asks that the Department consider the following comments prior to finalizing the amendments to 25 Pa. Code Chapter 95:

- 1) In developing the definition of new or increased discharge under 25 Pa. Code §95.10(a), the Department has not given consideration to multiple factors relevant to the Pharmaceutical and Chemical manufacturing industries as well as various other industries throughout the Commonwealth.

25 Pa. Code §95.10(a) states:

"For the purpose of implementing this section, a new discharge of High-TDS wastewater is a discharge that did not exist on April 1, 2009, and includes a TDS concentration that exceeds 2,000 mg/L or a TDS loading that exceeds 100,000 pounds per day. The term "new discharge" shall include an additional discharge, an expanded discharge or an increased discharge from a facility in existence prior to April 1, 2009"

- a) Many industries throughout the Commonwealth operate batch processes in production campaigns. Campaigns are dictated by product demand and the introduction of new product lines.

By defining a "new discharge" of High-TDS wastewater as an increased discharge from a facility in existence prior to April 1, 2009; the Department has not given consideration to campaign production and potential business growth opportunities for those existing dischargers with NPDES permits.

By the Department's definition, a process which generates wastewater with TDS concentrations greater than 2,000 mg/L that has been produced in past campaigns (or even one day prior to April 1, 2009) and was not being produced on April 1, 2009 would be an increased discharge when the production campaign resumes even though this product has been produced in campaigns prior to April 1, 2009.

The Department's definition of "new discharge" of High-TDS wastewater also has the potential to limit new product introduction to industrial facilities. Wastewater generated from new process would be considered a "new discharge" of High-TDS wastewater (assuming TDS concentrations greater than 2,000 mg/L). Considering the cost of treatment of High-TDS wastewater, industrial facilities may decline business growth opportunities because the cost of wastewater treatment may be greater than the value of the product.

The Department needs to make provisions to ensure that the definition of a new or increased discharge does not include wastewater from production campaigns that have been produced in prior years and does not limit new product introduction at existing facilities.

- b) The economic conditions throughout the Commonwealth have caused many industries to reduce or curtail production from levels that were existent prior to April 1, 2009. These decreased production levels have decreased TDS loadings from wastewater treatment facility discharges. As such, discharges in existence on April 1, 2009 are not representative of what could be expected during normal levels of production during stronger economic conditions.

During the NPDES permit application process, the Department evaluates each discharge at design flow conditions to ensure that water quality is protected. Not considering the design flow rate of treatment plants in the definition of existing discharge penalizes industries from returning to past production levels.

The Department needs to consider revisions to the definition of existing discharge to include TDS wastewater streams from higher production levels in existence prior to April 1, 2009. The use of the wastewater treatment facility design flow and a defined maximum TDS wastewater loading from past production would be more appropriate and would provide industry opportunities to return to prior production levels.

- 2) In developing the technology based effluent limitations for TDS, chlorides, and sulfates under 25 Pa. Code Chapter 95, the Department has not considered the immediate and long range economic impact upon the Commonwealth and its Citizens, as required by the Clean Streams Law (35 P.S. 691.5(a)(5)). The Department has estimated (39 Pa. B. 6467) the cost of treating high TDS wastewater to be on the order of \$0.25/gallon treated. In implementing the revisions

to Chapter 95 and the High TDS Wastewater Strategy, the Department has applied the technology based standards for TDS, Chlorides, and Sulfates to the entire facility discharge for those facilities who apply to increase discharges of high TDS wastewater (Wyoming Valley Sanitary Authority).

The rated capacity of Cherokee Pharmaceuticals' industrial wastewater treatment facility is 2.1 million gallons per day. Using the Department's cost estimates, the cost to treat this wastewater stream would be approximately \$525,000 per day or nearly \$200 Million per year. Costs of this magnitude would severely impact if not destroy the economic viability of numerous industries across the Commonwealth. Companies would be forced to pass these costs on to their customers, who will in turn seek more competitively priced products made in locations outside Pennsylvania.

It is important for the Department to also take into consideration that the dewatered substances will need to be properly disposed, adding additional costs to wastewater treatment facilities. We recommend that the Department analyze the cost of disposal, the impact on landfills, the need for future expansion of landfills, as well as the potential need for the development of additional landfills. We believe that the long term impact on landfill space needs to be determined prior to the adoption of the Chapter 95 revisions.

The long range economic strategy for the Commonwealth must include maintaining current industry and allow for growth of these existing industries.

By defining a "new discharge" as an increase of High-TDS wastewater from an existing facility, the Department will not allow for growth within the Commonwealth's existing industrial base. This will jeopardize the long-range economic viability of the Commonwealth's industries.

- 3) Wastewater discharges from the Pharmaceutical Industry (and various other point source categories throughout the Commonwealth) are currently regulated under industry specific federal Effluent Limitation Guidelines (ELG's) promulgated by EPA. The revisions to Chapter 95 state the following with respect to EPA's ELG's (§95.10(b)(6)):

"Discharges of wastewater produced from industrial subcategories with applicable Effluent Limit Guidelines for TDS, Chlorides or Sulfates established as Best Available Technology Economically Achievable (BAT), Best Conventional Pollutant Control Technology (BCT), or new source standards of performance, by the Administrator of the EPA under sections 303(b) and 306 of the Federal Act (33 U.S.C.A §§ 1314(b) and 1316) are exempt from the effluent standards in this section."

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"

EPA's technical development document for the Pharmaceutical Manufacturing Point Source Category notes that Pharmaceutical production is likely to generate acids and bases and that these wastewaters are likely to require chemical pretreatment prior to biological treatment. The use of acids, bases, and chemical pretreatment are the major TDS, chloride and sulfate containing wastewater generating steps resulting from pharmaceutical production.

Under 33 U.S.C.A. §§ 1316, EPA evaluated these wastewater generating steps and a determined that regulation for TDS, sulfates, and/or chlorides was either not necessary or cost prohibitive.

We propose that the Department consider EPA's evaluation during the ELG development process and revise 25 Pa. Code §95.10(b)(6) to exempt all industrial point source categories already regulated under EPA's Effluent Limitation Guidelines regardless of whether there are ELG's for chlorides, TDS, or sulfates.

- 4) The Food and Drug Administration (FDA) requires strict control of pharmaceutical processes and ingredients. These requirements include production of de-ionized water for processing, and cleaning of process equipment with strong acids and bases.

Both of these processing steps produce large TDS loadings that are directed to industrial wastewater treatment plants. Prior to discharge to surface waters, these strong acids and bases are neutralized to meet NPDES permit requirements for pH, which adds additional TDS loading. As discussed above, during the ELG development process EPA evaluated these process streams and determined that ELG's for TDS, Chlorides, or Sulfates were not warranted.

Any new processes would require the same level of FDA controls and, as such, would likely meet the Department's definition of an increased discharge of High-TDS wastewater. The controls required by FDA for this production would directly conflict the Department's requirement for TDS control.

If the proposed definition for an increased discharge of High-TDS wastewater is finalized as written, the Department will negatively impact the development and commercialization of new pharmaceutical ingredients by limiting production methods.

- 5) The revisions to 25 Pa. Code Chapter 95 are conflicting with many of the Department's other regulatory programs. In particular, chemical scrubbing is required by the Department's air quality program and EPA's Pharmaceutical MACT to reduce hazardous air pollutant emissions.

Under the Department's definition of "new discharge" of High-TDS wastewater, installation of an acid gas scrubber to comply with air quality regulations that discharges wastewater with TDS loadings greater than 2,000 mg/L to an industrial wastewater treatment plant would be considered a "new discharge" of High-TDS

wastewater. Other air pollution control equipment with aqueous streams would likely fall under this definition as well. The Department needs to provide provisions for industries to install air pollution control equipment without the wastewater discharges being considered High-TDS wastewaters.

- 6) The revisions to Chapter 95 require treatment of High-TDS wastewaters to meet secondary drinking water standards for TDS, sulfates, and chlorides. This level of treatment is not required as the Department already has regulatory mechanisms in place to ensure that public water supplies are protected.

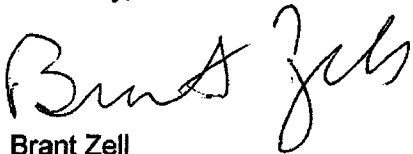
Using the Chapter 93 water quality standards, the Department currently uses PENTOX modeling to predict if water quality based effluent limits (WQBELS) are warranted for protection of public water supply use of receiving water bodies. The model uses in-stream water quality criteria to ensure that public water supply intake levels do not exceed the water quality criteria specified in Chapter 93. This modeling is conducted by Department engineers with every NPDES permit application.

In cases where influent water to water suppliers exceeds the Chapter 93 water quality criterion, the Department has additional regulatory mechanisms under Chapter 96 to implement Total Maximum Daily Loads (TMDL's) on watersheds.

The Department has been successful in protecting and improving water quality across the Commonwealth using the regulatory mechanisms currently available in Chapters 93 and 96 and should continue water quality protection using these methods without revising Chapter 95.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Brant Zell". The signature is written in a cursive, somewhat stylized font.

Brant Zell

Cc: Northumberland County Commissioners
Montour County Commissioners
Representative Merle Phillips
Senator John Gordner
Senator Mary Jo White