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**From:** Forsgren, Lee [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A055D7329D5B470FBAA9920CE1B68A7D-FORSGREN, D]  
**Sent:** 5/14/2018 5:40:04 PM  
**To:** Smith, Brooks M. [Brooks.Smith@troutmansanders.com]  
**CC:** Wood, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2676c137cf54db0a5d98df232901821-Wood, Robert]  
**Subject:** RE: CVS Pharma ELG Question

Brooks,

We have had a couple of conversations internally and things are more complicated than I thought. Would suggest that you reach out to Rob Wood from my office and we can work through some of the complexities.

Regards,  
Lee

**D. Lee Forsgren**

Deputy Assistant Administrator  
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Environmental Protection Agency  
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Room 3219 WJCE  
Washington, DC 20460  
Phone: 202-564-5700  
[Forsgren.Lee@epa.gov](mailto:Forsgren.Lee@epa.gov)

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**From:** Smith, Brooks M. [mailto:Brooks.Smith@troutmansanders.com]  
**Sent:** Monday, May 14, 2018 1:15 PM  
**To:** Forsgren, Lee <Forsgren.Lee@epa.gov>  
**Subject:** CVS Pharma ELG Question

Hi Lee, I'm just circling back from our very productive meeting in late March to see if there is any news on your end. Thanks so much for looking into this. Best, Brooks

**Brooks M. Smith**

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Direct: Ex. 6  
[brooks.smith@troutman.com](mailto:brooks.smith@troutman.com)

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**From:** Smith, Brooks M.  
**Sent:** Tuesday, March 27, 2018 10:08 AM  
**To:** Forsgren, Lee <Forsgren.Lee@epa.gov>  
**Cc:** Penman, Crystal <Penman.Crystal@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>  
**Subject:** RE: Pharma ELG Question

Hello Lee, I look forward to seeing you on Friday. I'll be joined by an in-house environmental lawyer from CVS, Liz Ash.

We'd like to discuss the effluent guidelines for the Pharmaceutical Manufacturing Category in 40 CFR Part 439 and their applicability (or non-applicability) to certain small-scale, patient-specific preparations of a drug that are compounded by a compounding pharmacist. These activities occur at CVS's Coram and Omnicare operations (both of which are pharmacies). Generally, instruments and equipment used in this kind of compounding process are cleaned, after which any de minimis amount of residual drugs left on the instruments may be washed down the sink. EPA has identified equipment and instrument wash water as a potential source of wastewater for purposes of Subpart D (mixing, compounding, or formulating), which might be read to apply to CVS's activities. However, EPA's regulations and guidance are less clear regarding whether such equipment and instrument wash water is a process water subject to the regulations under Part 439, particularly in de minimis amounts. We believe that in our particular scenario, EPA did not intend for Part 439 to apply. We'd be most grateful for any guidance, direction or clarification that EPA can provide on this issue.

We'll be prepared to explain all of this in more detail when we meet.

Best, Brooks

**Brooks M. Smith**

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**From:** Forsgren, Lee [<mailto:Forsgren.Lee@epa.gov>]

**Sent:** Tuesday, March 13, 2018 1:34 PM

**To:** Smith, Brooks M. <[Brooks.Smith@troutmansanders.com](mailto:Brooks.Smith@troutmansanders.com)>

**Cc:** Penman, Crystal <[Penman.Crystal@epa.gov](mailto:Penman.Crystal@epa.gov)>; Campbell, Ann <[Campbell.Ann@epa.gov](mailto:Campbell.Ann@epa.gov)>

**Subject:** RE: Pharma ELG Question

Brooks,

I would be happy to try to find a time to speak with you. Crystal Penman will do her best to find a time that works for all concerned.

Regards,

Lee

**D. Lee Forsgren**

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**From:** Smith, Brooks M. [<mailto:Brooks.Smith@troutmansanders.com>]

**Sent:** Tuesday, March 13, 2018 12:48 PM

To: Forsgren, Lee <[Forsgren.Lee@epa.gov](mailto:Forsgren.Lee@epa.gov)>

Subject: Pharma ELG Question

Greetings Lee, I had the pleasure of seeing you a few times late last year, first at the annual VMA industry environmental conference in Richmond, and then at the NACWA clean water law conference down in Savannah.

I am dealing with an issue for our client, CVS, and I was hoping you might be willing/available to meet and brainstorm potential solutions. The specific issue involves some confusion over the older, existing effluent guidelines for the pharma manufacturing category (40 CFR Part 439), which we think can be resolved with some simple, clarifying guidance. This issue is not in any dispute or litigation – we're just hoping to have some clarification in order to avoid potential conflicts in the future.

Would you be willing to meet? If so, I'd be pleased to coordinate a time and send some background info on the issue. All my best, Brooks

**Brooks M. Smith**

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