

## Eckoff, Michael

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**From:** Eckoff, Michael  
**Sent:** Monday, May 23, 2016 3:24 PM  
**To:** 'Lapic, Kyle A'  
**Cc:** Buckley, Charles P; Green, James F; Hall, Daniel K.  
**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Okay, thanks for explanations.

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**From:** Lapic, Kyle A [mailto:KLapic@triumvirate.com]  
**Sent:** Friday, May 20, 2016 3:54 PM  
**To:** Eckoff, Michael <Michael.Eckoff@dep.state.fl.us>  
**Cc:** Buckley, Charles P <CBuckley@triumvirate.com>; Green, James F <jgreen@triumvirate.com>; Hall, Daniel K. <Daniel.K.Hall@dep.state.fl.us>  
**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Mr. Eckoff,

The profiles TO32140 and TO32139 were created by Triumvirate Environmental based off of the information provided from Prime Therapeutics master list of pharmaceuticals which was provided in the 5/6/16 email (Prime Therapeutics Master Inventory). The packing lists attached in the 5/17/16 email enclosed the contents of that drums which were created by Prime Therapeutics. The employees of Prime Therapeutics segregate, package, and create their own hazardous and non-hazardous waste streams.

In response to your question about intact and broken pharmaceuticals; it is difficult for me to elaborate as I do not want to speculate on Prime Therapeutics best management practices of overclassifying damaged or broken pharmaceuticals. To the best of my knowledge the generator Prime Therapeutics over classified the broken Capecitabine 500 mg tab, Capecitabine 500 mg tablet, and Enbrel 50 mg/mL Sureclick as hazardous pharmaceuticals as part of their management practice.

Let me know if you should have any additional questions.

Thank you



**Kyle Lapic**  
**EHS & Transportation Compliance Specialist**  
**Triumvirate Environmental**  
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**From:** Eckoff, Michael [mailto:Michael.Eckoff@dep.state.fl.us]  
**Sent:** Thursday, May 19, 2016 1:35 PM  
**To:** Lapic, Kyle A <KLapic@triumvirate.com>  
**Cc:** Buckley, Charles P <CBuckley@triumvirate.com>; Green, James F <jgreen@triumvirate.com>; Hall, Daniel K. <Daniel.K.Hall@dep.state.fl.us>  
**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Thank you Mr. Lapic,

In your letter dated May 6, 2016 you stated that Prime Therapeutics received the profiles (TO32140 and TO32139) which were created by TEI.

I don't understand how pharmaceuticals are hazardous waste when broken or unusable and non-hazardous waste when intact. Would you please elaborate.

Thank you,  
Michael

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**From:** Lapid, Kyle A [<mailto:KLapid@triumvirate.com>]  
**Sent:** Wednesday, May 18, 2016 3:42 PM  
**To:** Eckoff, Michael <[Michael.Eckoff@dep.state.fl.us](mailto:Michael.Eckoff@dep.state.fl.us)>  
**Cc:** Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>; Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>  
**Subject:** FW: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Good Afternoon Mr. Eckoff,

To clarify, Prime Therapeutics makes the waste determination on their site and packages accordingly before shipping to Triumvirate Environmental. The packing slips which indicate hazardous and non-hazardous are prepared by Prime Therapeutics.

Please find below the response to your follow-up questions.

- 1) The Forteo 600 mcg / 2.4mL was not known by the generator as a hazardous material and has now been corrected and will be placed into the hazardous profile.
- 2) The Capecitabine 500 mg tab (NDC 00378-2512-78); Capecitabine 500 mg tablet (NDC 00093-7474-89); and Enbrel 50 mg/mL Sureclick (NDC 58406-0445-04) were placed into the hazardous profile as these items were broken and unusable. The same three products were listed on the non-hazardous list as these items were intact medications and classified as non-hazardous.

Please let me know if you have any additional questions.



**Kyle Lapid**  
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**From:** Eckoff, Michael [<mailto:Michael.Eckoff@dep.state.fl.us>]  
**Sent:** Wednesday, May 18, 2016 8:15 AM  
**To:** Lapid, Kyle A <[KLapid@triumvirate.com](mailto:KLapid@triumvirate.com)>; Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>  
**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>  
**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Hello Mr. Lapid,

Thank you for submitting the waste profile information. I have the following comment regarding the profile:

1. Forteo 600 mcg/2.4 mL listed on page 3 of the profile was identified as non-hazardous waste. Forteo was found to exhibit the hazardous waste characteristic of toxicity for m-cresol, EPA waste code D024.

A copy of all corresponding information related to manifest #007703007 FLE was received during the inspection. In the packet was three pages of a list of both non-hazardous and hazardous pharmaceuticals. Three pharmaceuticals on the list are identified as both non-hazardous and hazardous wastes:

1. On page 1, Capecitabine 500 mg tab (NDC 00378-2512-78)
2. On page 1, Capecitabine 500 mg tablet (NDC 00093-7474-89)
3. On page 2, Enbrel 50 mg/mL Sureclick (NDC 58406-0445-04)

Please explain these discrepancies.

As stated in Part II Subpart A number 5.a. of the permit: The Permittee is liable for waste profiles supplied to generators.

Please provide a response by Friday, May 27, 2016.

Thank you,  
Michael

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**From:** Lapid, Kyle A [<mailto:KLapid@triumvirate.com>]

**Sent:** Tuesday, May 17, 2016 11:27 AM

**To:** Eckoff, Michael <[Michael.Eckoff@dep.state.fl.us](mailto:Michael.Eckoff@dep.state.fl.us)>; Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>

**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>

**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Good Morning Mr. Eckoff,

I apologize for the delay as I was out of the office all last week. Please find attached the list of non-hazardous pharmaceuticals that correspond to profile #TO32139 which you requested.

Let me know if you should have any additional questions.

Thank you



**Kyle Lapid**  
**EHS & Transportation Compliance Specialist**  
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**From:** Eckoff, Michael [<mailto:Michael.Eckoff@dep.state.fl.us>]

**Sent:** Tuesday, May 10, 2016 9:52 AM

**To:** Lapid, Kyle A <[KLapid@triumvirate.com](mailto:KLapid@triumvirate.com)>; Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>

**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>

**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Hello Mr. Lapid,

I've had a chance to review the information you sent and have one question for you.

Do you have the list of non-hazardous pharmaceuticals that correspond to profile #TO32139? If so, please submit a copy.

Thank you,  
Michael

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**From:** Lopic, Kyle A [<mailto:KLopic@triumvirate.com>]

**Sent:** Friday, May 06, 2016 1:44 PM

**To:** Eckoff, Michael <[Michael.Eckoff@dep.state.fl.us](mailto:Michael.Eckoff@dep.state.fl.us)>; Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>

**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>

**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Good Afternoon Mr. Eckoff,

Please find attached the response letter which addresses each of your questions. Along with the response letter we have also attached supporting documentation which corresponds to the questions.

Please let me know if you have any additional questions or comments.

Thank you



**Kyle Lopic**  
**EHS & Transportation Compliance Specialist**  
**Triumvirate Environmental**

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**From:** Eckoff, Michael [<mailto:Michael.Eckoff@dep.state.fl.us>]

**Sent:** Wednesday, April 27, 2016 1:25 PM

**To:** Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>

**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>; Lopic, Kyle A <[KLopic@triumvirate.com](mailto:KLopic@triumvirate.com)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>

**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Hello Mr. Buckley,

Thank you for the information you sent. I have a few more questions for you.

1. Manifest 007703007 FLE
  - a. Please provide a list of pharmaceuticals for profile #TO32139.
  - b. Did Triumvirate provide profiles #TO32140 and #TO32139 to Prime Therapeutics?
2. April 20, 2016 email
  - a. Have the accumulation areas containing transfer waste been clearly marked with signage and stanchions?
  - b. Please provide an update on the manifest discrepancy report and the unmanifested waste report.
3. Additional inspection observations
  - a. One 55-gallon drum of hazardous waste toxic liquid organic (chloroform and formalin) was located in Row 101. The drum was moved to an appropriate location during the inspection. According to the Preparedness and Prevention Plan, in the permit application, the northwest subunit will store only non-hazardous wastes.
  - b. One drum in Row 103, ten drums in Row 104, and one drum in Row 204 were positioned where the labels were not facing out (see #2 under Hazardous Waste in the April 20, 2016 email) Please provide documentation that this was corrected. The drum in Row 204 was immediately repositioned to face the label out.
  - c. A review of the weekly inspection logs revealed a note regarding cell capacity exceeded without referencing when it was corrected [40 CFR 264.15(d)].

Please respond by Friday, May 6, 2016.

Thank you,  
Michael

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**From:** Buckley, Charles P [<mailto:CBuckley@triumvirate.com>]  
**Sent:** Friday, April 22, 2016 3:15 PM  
**To:** Eckoff, Michael <[Michael.Eckoff@dep.state.fl.us](mailto:Michael.Eckoff@dep.state.fl.us)>  
**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>; Lopic, Kyle A <[KLopic@triumvirate.com](mailto:KLopic@triumvirate.com)>; Green, James F <[jgreen@triumvirate.com](mailto:jgreen@triumvirate.com)>  
**Subject:** RE: Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Good Afternoon Mr. Eckoff and Mr. Hall:

Thank you for your follow-up on the inspection.

Per your request the following document are attached:

1. TEI's most recent approved closure cost estimate
2. Financial assurance approval letter from FDEP dated June 9, 2015
3. Profile# TO32140: UPW pharmaceutical profile from manifest # 007703007 FLE (Prime Therapeutics).
4. Profile# TO32139: Non-RCRA pharmaceutical waste from manifest# 007703007 FL (Prime Therapeutics).

Please don't hesitate to let me know if you have any questions. Thanks and have a great weekend!

Best Regards,  
Kip Buckley



**Charles Buckley**  
**Operations Manager**

**Triumvirate Environmental**

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**From:** Eckoff, Michael [<mailto:Michael.Eckoff@dep.state.fl.us>]  
**Sent:** Wednesday, April 20, 2016 1:36 PM  
**To:** Buckley, Charles P <[CBuckley@triumvirate.com](mailto:CBuckley@triumvirate.com)>  
**Cc:** Hall, Daniel K. <[Daniel.K.Hall@dep.state.fl.us](mailto:Daniel.K.Hall@dep.state.fl.us)>  
**Subject:** Triumvirate Environmental Inc - RCRA inspection - April 13 and 14, 2016

Hello Mr. Buckley,

I apologize for the delay in getting this to you.

Thank you for your time during the inspection. Below are some highlights regarding the inspection:

#### Solid Waste

1. Although a paper copy of the current solid waste permit was not on-site, the permit is accessible through OCULUS.
2. Please provide a copy of the current approved financial assurance.

#### Hazardous Waste

1. Two 5-gallon containers were identified in a trailer that has been designated as your transfer facility. The following day, a list of containers located in your transfer facility was reviewed. The two 5-gallon containers were not listed [62-730.171(6), F.A.C.]. You stated the containers were being shipped from the TSDF but were placed in the transfer station prior to placement on the trailer being loaded for shipment. In addition, as required in permit condition Part II Subpart B.1, number 8., accumulation areas containing transfer waste shall be clearly marked with signage and stanchions.
2. Two 30-gallon drums in Row 303 were positioned such that the labels were not facing out [403.727(1)(c), F.S.]. As required in permit condition Part II Subpart B.2, number 9., containers shall not be placed or stored in a manner that could obstruct inspection... In addition, according to II.B.4 of the permit application, drums on a pallet are stored with hazardous waste labels faced toward the aisle, and Figure II B 4 Weekly Inspection Log, in the permit application, labels are checked to ensure they are facing out. The drums were immediately re-positioned to make the labels visible for inspection.
3. Please provide a copy of the waste profile for the wastes listed on manifest #007703007 FLE (Prime Therapeutics).
4. Two things regarding the scenario you described during the records review of hazardous waste from two large quantity generators arriving on one manifest: first, a manifest discrepancy report must be completed for the manifest that was received with the incorrect number of containers listed, in accordance with permit condition Part II Subpart A, number 4.a.(1), and 40 CFR 264.72; and an unmanifested waste report must be filed for the waste from the other generator that did not arrive with a manifest, in accordance with permit condition Part II Subpart A, number 4.a.(2), and 40 CFR 264.76.

Daniel – please add any potential issues you noted.

This may not be a complete list of potential issues, subsequent requests may follow.

Please respond, where appropriate, to the above items by Friday, April 29, 2016. If a response to a particular item cannot be provided by April 29, 2016, please provide a schedule outlining dates the information will be provided.

Thank you,



**Michael Eckoff**  
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