### **Andy Bray**

From: Yeman, William (DEC) <william.yeman@dec.ny.gov>

**Sent:** Sunday, June 21, 2015 4:23 AM

To: Stephan

Cc: Treers, Melissa (DEC); Ottaway, William (DEC)
Subject: Re: DrugDisposeAll solid waste request letter

## Stephan,

In reply to your question "If P&U listed meds were removed from the DrugDisposal Test Report would that also satisfy your concerns over our message?", we would need to say that it would not completely satisfy our concerns in part because I don't see that you recognize how hazardous wastes may wind up being rendered non-hazardous waste *yet still don't meet the Land Disposal Restrictions* ("LDRs"). [This was touched upon in my 6/18 email's paragraph starting with "Note that even...") It may seem counter-intuitive, but non-hazardous wastes can still have remaining hazardous waste requirements that need to be met. (That came about because of some changes Congress made in 1984.)

Also, even though you do state that "...we do stress to interested parties that this is intended for non-hazardous controlled substances and does NOT replace any of their *current* pharmaceutical wastes streams they have in place for hazardous waste (P, U, or characteristic) or general pharma waste" that message needs to be put in writing in the literature packages and prominently presented to potential customers. This will ultimately help not only your potential customers but your company as well because your products would avoid being at the center of a customer's hazardous waste violations.

Sincerely,
Bill Yeman
NYSDEC
Albany NY
william.yeman@dec.ny.gov
(518-402-9594 - direct #)

From: Stephan <stephan.thibodeau@gfmd.com>

Sent: Thursday, June 18, 2015 9:08 PM

To: Yeman, William (DEC)

**Cc:** Treers, Melissa (DEC); Ottaway, William (DEC) **Subject:** Re: DrugDisposeAll solid waste request letter

Mr Yeman,

Thank you very much for your feedback. We share your concern over proper disposal of ALL wastes and protecting the environment. Disposal Technologies was forged out of a concern over the growing number of pharmaceuticals contaminating our water resources. We are eager to clarify & make necessary changes so that facilities can properly dispose of their non-hazardous controlled substances and not violate any regulations in doing so.

Regarding the use of DrugDisposeAll® please note that **we do stress** to interested parties that this is **intended for non-hazardous controlled substances** and does NOT replace any of their *current* pharmaceutical wastes streams they have in place for hazardous waste (P, U, or characteristic) or general pharma waste. This message has been clear and easily received by facilities in other stats. We explain to facilities that they should **continue** to dispose of those wastes using current acceptable protocols for hazardous and general pharma wastes that are non-hazardous. We stress to them that DrugDisposeAll® fills the gap in the waste stream for **non-hazardous controlled substances** that, even now, the *vast majority of facilities are flushing down the drain because of the void of acceptable alternatives*. Thus DrugDisposeAll® presents a great option for ecofriendly wasting that renders those non-hazardous controlled substances non-retrievable.

The email submitted did contain several attachments and material that would be shared with agencies like yourself. This data, however, such as the *DrugDiposeAll Test Report 10.14.2015.pdf*, is NOT provided to customers indiscriminately. It is shared, when appropriate, in the context of discussions about the efficacy of DrugDiposeAll® and what is appropriately disposed of in the DrugDiposeAll® containers (*as you noted there is a caution on the product literature about hazardous materials <u>but also</u> in the DrugDiposeAll Test Report 10.14.2014.pdf). We explain that should a hazardous material accidently be placed in DrugDisposeAll® then the entire container would be regulated as hazardous and must be handled appropriately under all applicable regulations.* 

Again, though ultimately the waste generator is responsible for determining if their waste is hazardous waste, regardless of disposal system, we stress to healthcare facilities that have adopted DrugDisposeAll® in other states that it is intended for non-hazardous controlled substances, the missing gap in their current pharma waste stream. This message has readily been received by facilities and the internal departments we have worked with in other states including Pharmacy, Nursing, Environmental Services, and Staff Education.

I hope this helps alleviate your concern over the message we are sending to facilities. If P&U listed meds were removed from the DrugDisposal Test Report would that also satisfy your concerns over our message?

Thank you again for your feedback and I look forward to your reply.

Best regards, Stephan

From: Yeman, William (DEC)

**Sent:** Thursday, June 18, 2015 11:30 AM **To:** stephan.thibodeau@gfmd.com

**Cc:** <u>Treers, Melissa (DEC)</u>; <u>Ottaway, William (DEC)</u> **Subject:** RE: DrugDisposeAll solid waste request letter

#### Mr Thibodeau:

Melissa Treers has asked that I take a look at your June 16 submittal from the standpoint of the RCRA Hazardous Waste regulations to be sure that there would not be issues related to those regulations. (Melissa is involved with *non-hazardous* waste disposal here at NYSDEC and I'm essentially her counterpart for *Hazardous* Waste disposal.)

One precondition for DrugDisposeAll containers to be acceptable for disposal as solid waste in NYS is that they contain no hazardous waste (and also that the waste has met all applicable EPA LDR ["Land Disposal Restrictions"] requirements). Although some of your attachments suggest that the DrugDisposeAll containers are to be used only for

DEA Controlled Substances, other attachments indicate otherwise. Thus, customers using your DrugDisposeAll containers would receive "mixed signals" regarding what should be placed inside. For example, your attachment "DrugDisposeAll solid waste request.pdf" – i.e., your June 16 letter of request to Melissa – states that "Drug Dispose All® is intended for the disposal of non-hazardous controlled substances", yet your attachment "Talem Test Recap.pdf" shows that tests of the DrugDisposeAll containers employed such pharmaceuticals as Metoprolol Tartrate, which is *not* a DEA Controlled Substance. This obviously could 'send signals' to your customers that the DrugDisposeAll containers can be used for *non*-Controlled Substances too; *some of those waste pharmaceuticals that the customer places in the containers may be hazardous waste.* In fact, your attachment "DrugDisposeAll Test Report 10 15 14 .pdf" shows that Nicorette Lozenges and warfarin – both non-Controlled Substances *but both P-listed hazardous wastes* -- were also used for testing of DrugDisposeAll containers, further suggesting to your customers that DrugDisposeAll containers can be used for non-Controlled Substances *that are hazardous* waste. Also suggesting to the customer that DrugDisposeAll containers may also be used for *non*-Controlled Substances is the 'MSDS Sheet' for your product – i.e., your attachment "DDA\_SDS\_US\_011615\_FINAL.pdf" -- which identifies the Product Use as follows: "To dispose of and render inert out-of-date or unused medications", i.e., with no mention of any restriction that it not be used for the disposal of non-Controlled Substances or hazardous wastes.

Hence, we would anticipate that your customers in New York State will sometimes place hazardous waste pharmaceuticals in your DrugDisposeAll containers, and we would anticipate then having these containers sometimes placed in the solid waste stream (which would likely be a violation). While it is true that one of your attachments ("Drug Dispose All literature\_update052015.pdf") does mildly caution the reader on the last page that "for all P&U list hazardous waste items, please follow all Federal, State and Local guidelines for final disposal" – incidently, I found no similar cautionary notes in any of your other attachments -- there is no similar cautionary note for *characteristically* hazardous pharms. [An example of a likely characteristically hazardous pharmaceuticals would be high-alcohol pharmaceutical wastes (which we recognize would likely be placed in your "DrugDisposeAll-ForLiquids" product and not your "DrugDisposeAll" product). Other examples are silver-containing and lindane-containing pharmaceuticals.]

Note that even in those instances where the DrugDisposeAll units render characteristically hazardous wastes to be non-hazardous (perhaps sometimes through dilution), there are still LDR requirements that must be met. For example, a high-alcohol pharmaceutical waste is likely to fall into what is called the "D001-highTOC" subcategory, which precludes such hazardous wastes from being landfilled even when rendered non-hazardous in a DrugDisposeAll (or DrugDisposeAll-ForLiquids) container.

The bottom line is that the data you supplied in your June 16 email to Melissa is not at all sufficient to show that DrugDisposeAll containers disposed in New York are non-hazardous waste and in compliance with EPA's LDR requirements. As mentioned above, these two requirements are a precondition for DrugDisposeAll containers to be acceptable for disposal as solid waste in New York State. Hence, we cannot provide you with the acceptance requested in your June 16 letter to Ms Treers.

Please email any follow-up questions or comments you have to me at william.yeman@dec.ny.gov

Bill Yeman NYSDEC Albany NY <u>William.yeman@dec.ny.gov</u> (518-402-9594 – desk #)

From: Stephan [mailto:stephan.thibodeau@gfmd.com]

Sent: Tuesday, June 16, 2015 9:28 AM

**To:** Treers, Melissa (DEC)

Subject: DrugDisposeAll solid waste request letter

Good morning Ms Treers,

As discussed previously on the phone I am attaching a formal letter requesting acceptance of used DrugDisposeAll containers to be disposed of as solid waste in NYS. The system is recommended to render NON-hazardous controlled substances non-retrievable and eco-friendly. Many facilities are anxious to use our product to help avoid environmental contamination as well as prevent drug diversion, increasing patient safety.

#### Attached are the following:

- solid waste request letter
- DrugDisposeAll product literature
- DrugDisposeAll product summary page
- SDS
- Talem environmental testing results
- Talem paint filter test results
- Environmental testing summary page
- DrugDisposeAll test report (shows efficacy in sequestering pharmaceuticals)
- U of TX performance letter

I am available for further questions & would be happy to meet with yourself or anyone else on this matter. Thank you for your attention to this request. I look forward to your feedback.

Sincerely, Stephan

# Stephan Thibodeau

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