

November 30, 2020

John White
Florida Department of Environmental Protection
Central District Office
3319 Maguire Blvd. Suite 232
Orlando, FL 32803



Via Email

Subject: Response to FLD984171850 Daniels Sharpsmart Warning Letter

Daniels Sharpsmart, Inc. 111 West Jackson Blvd. Suite 1900 Chicago, IL 60604

Dear Mr. White,

Daniels provides essential services to the healthcare industry in North America, specifically in the safe containment, transport, and disposal of healthcare generated wastes. Safety and compliance have always been our highest priority and we pride ourselves on reducing injury while maintaining compliance with applicable regulation. As an essential business, our various teams within Daniels have also been responding to the current pandemic; by working very closely with our customers and staff to ensure continuous and safe service of healthcare generated wastes.

A RCRA File Review was conducted on 4/7/20 of Daniels for the site located at 10705 Rocket Blvd. Ste. 111 Orlando, FL 32824 (Daniels Orlando 10-day Facility). During this inspection, as mentioned within the Inspection Report, possible violations of Chapter 403, F.S., and Chapter 62-730, Florida Administrative Code (F.A.C.) were observed.

Daniels Sharpsmart, Inc. ("Daniels") is in receipt of the Warning Letter dated 11/2/20 from the Florida Department of Environmental Protection (Department). Daniels received the letter via email with request to contact John White within 7 days of receipt to arrange a meeting to discuss this matter. Further discussion occurred between Kyle Little, Daniels Compliance Manager and John White, FLDEP Environmental Consultant on 11/9/20, reviewing the possible violations. It was agreed that Daniels provide a written letter to the Department by 11/30/20 describing the facts of compliance.

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Please accept this letter as response to the possible violation(s) as referenced below:

1. Hazardous waste was stored on-site for greater than 10 days without a RCRA storage permit.
2. Incomplete manifests, without EPA identification numbers, and inaccurate manifests, with incorrect EPA identification numbers, were accepted for transport.
3. The transporter failed to ensure the manifest accompanied the hazardous waste during transport.
4. The contingency plan contained references to an inaccurate fire department for contact during an emergency.
5. Changes were made to manifests without the generator's knowledge or approval.
6. The 10-day transfer facility log was incomplete and inaccurate.

1. Hazardous waste was stored on-site for greater than 10 days without a RCRA storage permit.

Explanation (FLDEP): A transfer facility that stores hazardous waste on-site for greater than 10 days is subject to the permitting requirements for a hazardous waste storage facility. Review of hazardous waste manifests found the facility stored hazardous waste transported on manifest 000973892WAS for a period of 14 days without a RCRA storage permit. This exceedance was not documented in the facility's 10-day transfer facility log.

Response: Daniels Sharpsmart, Inc. operates as a hazardous waste transporter that stores manifested hazardous waste in proper containers at its transfer facility for ten (10) days or less. This operation is managed on-site by trained staff to ensure compliance with this requirement. In summary, manifested shipments of hazardous waste arrive at the Daniels Orlando 10-day Facility then are off-loaded by authorized personnel. All containers and associated shipping documentation (i.e. hazardous waste manifest) are processed accordingly by staff including manifest & container reconciliation. Containers are staged in the designated area within the facility for safety and security. All manifests are secured with the waste and recorded on a "Manifest Log". A weekly inspection is also completed documented on a log checking various items. To ensure containers are transferred from the site within 10-days, Daniels has established partnerships through contractual agreement with 3rd party transporters or may self-transport under applicable permits.



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After review of manifest# 000973892WAS, it was determined that the facility did not store hazardous waste identified on the manifest for greater than 10-days. The generator made an error when writing the date of pick-up on the manifest, writing “12/9/19”, instead of “12/19/19”. The actual pick-up date was confirmed by an internal review from our Logistics / Transportation software. Reviewing the actual manifest, Daniels driver (Transporter 1) signed and dated certifying the pick-up was made from the generator on 12/19/19. This is also the date the waste was transported to the Daniels Orlando 10-day Facility. Transporter 2 signed and dated certifying when the pick-up was made from the Daniels Orlando 10-day facility, which occurred on 12/23/20. Also attached is the LDR form for manifest# 000973892WAS, which was signed by the generator on 12/19/20 (attachment A). The waste on manifest# 000973892WAS was in fact on-site at the Daniels transfer facility for less than 10 days.

2. Incomplete manifests, without EPA identification numbers, and inaccurate manifests, with incorrect EPA identification numbers, were accepted for transport.

Explanation (FLDEP): A transporter may not accept hazardous waste from a generator unless the transporter is also provided with a manifest form (EPA Form 8700–22, and if necessary, EPA Form 8700–22A) signed in accordance with the requirement of §262.23, or is provided with an electronic manifest that is obtained, completed, and transmitted in accordance with §262.20(a)(3) of this chapter, and signed with a valid and enforceable electronic signature as described in 40 CFR 262.25. Review of hazardous waste manifests found 25 incomplete manifests were accepted by Daniel's Sharpsmart between November 2019 and March 2020. Also, an additional 20 manifests with an incorrect EPA identification number were accepted by Daniels Sharpsmart during this same time period.

Response: Daniels partners with its customers to safely transport healthcare generated wastes in compliance with applicable regulation. In summary, before any hazardous waste is transported, a waste determination is made by the generator if a given waste is hazardous. Once the waste determination has been made, the generator will properly complete a waste profile form for pick-up. This form essentially lists out all the chemical properties of a particular type of waste. Additionally, during this initial process, Daniels requests specific information from the generator of the waste, including but not limited to generator name, address, and EPA ID#. This information is cross-referenced with US EPA resources for

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accuracy on the shipping documentation (i.e. hazardous waste manifest). Hazardous wastes, subject to manifesting requirements will comply with regulations in 40 C.F.R. Part 262 and Part 263.

Incomplete manifests, without EPA identification numbers

After review of hazardous waste manifests, the Department found 25 incomplete manifests that were accepted by Daniels between November 2019 and March 2020. All the manifests were accepted from AdventHealth Infusion Center Kissimmee (1300 West Oak Street, Suite A, Kissimmee, FL) and determined incomplete for not having an EPA identification number. During the initial customer set-up process, Daniels requested the generator status for this specific location to then include any applicable EPA ID# on the manifest. The customer then advised and continues to advise they are a Very Small Quantity Generator, therefore, not requiring an EPA ID# on the shipping document (i.e. hazardous waste manifest). However, it is our understanding that this specific location has applied for an EPA ID# as required to follow Subpart P regulation.

Also, for the referenced shipments of hazardous waste, Daniels was provided a hazardous waste manifest from the generator signed in accordance with the requirement of §262.23. The generator signed Box 15: *Generator's/Offeror's Certification* attesting the information is fully and accurately described on the manifest including Box 1: *Generator ID Number*.

As mentioned in the Inspection Report, respectfully, it is not common industry practice for the transporter to determine a generator's status based off the frequency of shipments and volume of hazardous waste. Hazardous waste fluctuates from shipment to shipment and quantity generated and quantity shipped from a healthcare facility may be different. VSQG's may generate 100 kilograms or less per month of hazardous waste or one kilogram or less per month of acutely hazardous waste and may not accumulate more than 1,000 kilograms of hazardous waste at any time. Therefore, the waste shipped on the manifest does not necessarily mean it was generated that month making it extremely difficult for a transporter to determine a generator's status.



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Inaccurate manifests, with incorrect EPA identification numbers

An additional 20 manifests with an incorrect EPA identification number were accepted by Daniels during this same time. Daniels had accepted manifests that read Apopka Inpatient EPA ID# FLD000229377, however, should read AdventHealth Apopka EPA ID# FLR000229377.

Advent Health had acquired Florida Hospital changing the name from Apopka Inpatient to AdventHealth Apopka. There was no notification from the generator to specifically update this information on the manifest. Respectfully, there is no way for a hazardous waste transporter to know the details of a customer business acquisition, including a legal name change.

AdventHealth is a healthcare facility that we value as a partner and have been together for a long time. We were unable to reference the initial customer set up information regarding the EPA ID#. The EPA ID# misplaced the "R" for a "D" and was determined to be a typo. These keys are next to each other on the computer keyboard. However, throughout the manifests, the generator signed Box 15:

Generator's/Offeror's Certification attesting the information is fully and accurately described on the manifest including Box 1: *Generator ID Number* and Box 5: *Generator's Name and Mailing address*.

The accurate EPA ID# and legal name of the generator has been updated on the hazardous waste manifest.



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3. The transporter failed to ensure the manifest accompanied the hazardous waste during transport.

Explanation (FLDEP): The transporter must ensure that the manifest accompanies the hazardous waste. Specifically, based on exception reports provided to the Department, hazardous waste manifests have disappeared during transport or failed to accompany the hazardous waste during shipment. Missing manifests include 000973721WAS signed by the generator on 12/6/19, manifest 001059213WAS signed by the generator on 2/3/20, and manifest 001059154WAS signed by the generator on 1/24/20.

Response:

Manifest Discrepancy Report – Manifest 000973721WAS:

On 2/21/20, a discrepancy report was received by the FLDEP for manifest# 000973721WAS. AdventHealth Orlando never received a return copy of manifest# 000973721WAS with a designated facility owner/operator signature. Upon notification from AdventHealth, Daniels began investigating the shipment as required.

Daniels serviced two generators on 12/6/19: AdventHealth Orlando and AdventHealth Altamonte. AdventHealth Orlando shipped three 55-gallon drums (recorded as, “165 gallons”) of waste alcohols on manifest 000973721WAS. AdventHealth Altamonte shipped two containers holding a total of ten gallons of waste alcohols on manifest# 000973725WAS. Both manifests were signed by AdventHealth completing Box 15: *Generator’s/Offeror’s Certification* and Daniels completing Box 17: *Transporter Acknowledgment of Receipt of Materials*.

On manifest# 000973725WAS, the number of waste alcohol containers had been changed from 2 to 3, and the total volume of waste shipped was changed from 10 gallons to 165 gallons. The initials on the manifest are “AS”, an administrator at the Daniels Orlando 10-day Facility.

As a result of the Daniels driver misplacing manifest# 000973721WAS, it was determined that the containers on that manifest were transferred to manifest# 000973725WAS at the Daniels Orlando 10-day Facility, erroneously removing the existing containers on manifest# 000973725WAS. It is believed the



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entire combined volume of waste alcohols from both AdventHealth Orlando and AdventHealth Altamonte were shipped on manifest# 000973725WAS from the Daniels Orlando 10-day Facility. A similar administrative error occurred as identified within Manifest Discrepancy Report - Manifest 001059154WAS. A driver had misplaced manifest# 001059154WAS, resulting in the containers on that manifest being transferred to manifest# 001059156WAS, erroneously removing the existing containers on manifest# 001059156WAS.

As mentioned, both manifests were signed by AdventHealth completing Box 15: *Generator's/Offeror's Certification* and Daniels completing Box 17: *Transporter Acknowledgment of Receipt of Materials*. It is our assumption since the Daniels driver signed certifying receipt of the materials and therefore had the hazardous waste manifest in his possession at the time, manifest# 000973721WAS did accompany the corresponding hazardous waste to the Daniels Orlando 10-day Facility, however, misplaced upon arrival gathering paperwork. Hazardous waste and manifests were then transferred off-site by 3rd party carrier.

The Daniels driver was in fact trained and certified, specifically regarding the importance of recordkeeping. However, due to an oversight the manifest was misplaced. Further discussion did occur between Daniels and the driver regarding this matter. The driver is currently no longer part of our team.

Please reference number 5 of this letter regarding corrective action to the changes that were made to manifests without the generator's knowledge or approval.



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Manifest Discrepancy Report - Manifest 001059213WAS:

On 3/20/20, a discrepancy report was received by the FLDEP for manifest# 001059213WAS. AdventHealth never received a return copy of manifest# 001059213WAS with a designated facility owner/operator signature. Daniels Sharpsmart, Inc. was initially contacted (via email) by AdventHealth on 3/16/20 to determine the status of the waste shipment. Upon notification from AdventHealth, Daniels began investigating the shipment as required.

On 2/3/20, seven "DF" type containers of "PHARMS" waste were shipped from AdventHealth Orlando on manifest# 001059213WAS. On 2/12/20, five "DF" type containers of "PHARMS" waste were shipped from AdventHealth Orlando on manifest# 001059283WAS. Both manifests were signed by AdventHealth completing Box 15: *Generator's/Offeror's Certification* and Daniels completing Box 17: *Transporter Acknowledgment of Receipt of Materials*. On 2/29/20, manifest 001059283WAS was signed by the designated receiving facility, Heritage Environmental (TSDF), as received with 12 containers of "PHARMS" waste, not five.

On 3/20/20, Daniels in partnership with Heritage Environmental (TSDF), replied to AdventHealth stating the following:

"Here is what I found for manifest 001059213WAS.

- Manifest 001059213WAS was never received by Charlotte. With a service date of 2/3, it would have been received on 2/12*
- 7 pieces were added to manifest 001059283WAS at the Orlando 10-day*
- Manifest 001059283WAS was received and processed as 12 total pieces by Heritage*

Your original manifest for 001059213WAS lists a total weight of 85 pounds, which is most likely black bins. I'm thinking they came back to Orlando and were added to the next Plaza stop with black bins instead of drums. This will account for all 7 pieces from manifest 001059213WAS."

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As a result of the Daniels driver misplacing manifest# 001059213WAS, it was determined that the containers on that manifest were transferred to manifest# 001059283WAS at the Daniels Orlando 10-day Facility. The initials on the manifest are "AS", an administrator at the Daniels Orlando 10-day Facility. The entire combined volume of "PHARMS" waste from AdventHealth Orlando were shipped on manifest# 001059283WAS.

As mentioned, both manifests were signed by AdventHealth completing Box 15: *Generator's/Offeror's Certification* and Daniels completing Box 17: *Transporter Acknowledgment of Receipt of Materials*. It is our assumption since the Daniels driver signed certifying receipt of the materials and therefore had the hazardous waste manifest in his possession at the time, manifest# 001059213WAS did accompany the corresponding hazardous waste to the Daniels Orlando 10-day Facility, however, misplaced upon arrival gathering paperwork. Hazardous waste and manifests were then transferred off-site by 3rd party carrier.

The Daniels driver was in fact trained and certified, specifically regarding the importance of recordkeeping. However, due to an oversight the manifest was misplaced. Further discussion did occur between Daniels and the driver regarding this matter. The driver is currently no longer part of our team.

Please reference number 5 of this letter regarding corrective action to the changes that were made to manifests without the generator's knowledge or approval.



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Manifest Discrepancy Report - Manifest 001059154WAS:

On 3/20/20, a discrepancy report was received by the FLDEP for manifest# 001059154WAS. AdventHealth Orlando never received a return copy of manifest# 001059154WAS with a designated facility owner/operator signature. Daniels Sharpsmart, Inc. was initially contacted (via email) by AdventHealth on 3/16/20 to determine the status of the waste shipment. Upon notification, Daniels began investigating the situation as required.

On 1/24/20, two "DF" type containers (recorded as, "427 P") of "PHARMS" waste were shipped from AdventHealth Orlando on manifest# 001059154WAS (attachment B). The copy of the manifest was signed by AdventHealth Orlando (Generator), Daniels Sharpsmart (Transporter 1), and Freehold Cartage (Transporter 2). Transporter 2 transferred the manifest and accompanying containers from the Daniels Orlando 10-day Facility on 1/27/20. Although there is no record of manifest# 001059154WAS on the Daniels manifest log, Transporter 2 signed the actual manifest indicated they had taken possession of it.

Also, on 1/24/20, 12 "DF" type containers (recorded as, "600 P") of "PHARMS" waste were shipped from AdventHealth Orlando on manifest# 001059156WAS (attachment C). The copy of the manifest was signed by AdventHealth Orlando (Generator), Daniels Sharpsmart (Transporter 1), and Freehold Cartage (Transporter 2). Transporter 2 transferred the manifest and accompanying containers from the Daniels Orlando 10-day Facility on 1/27/20. On manifest# 001059156WAS, the number of containers of "PHARMS" was later changed from 12 to 2.

On 1/31/20, 2 "DF" type containers (recorded as, 300 P") of "PHARMS" waste were shipped from AdventHealth Orlando on manifest# 001059200WAS (attachment D). The copy of the manifest was signed by AdventHealth Orlando (Generator), Daniels Sharpsmart (Transporter 1), and Freehold Cartage (Transporter 2). Transporter 2 transferred the manifest and accompanying containers from the Daniels Orlando 10-day Facility on 2/3/20. On manifest# 001059200WAS, the number of containers of "PHARMS" waste were later changed from 2 to 14.



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It was determined, once the two containers from missing manifest# 001059154WAS arrived at Heritage Environmental 10-day transfer facility in Charlotte, North Carolina they were added onto manifest# 001059156WAS. The 12 containers on manifest# 001059156WAS were removed from the manifest and later identified at Heritage Environmental 10-day transfer facility in Charlotte, North Carolina then added onto manifest# 001059200WAS. For all the referenced manifests, changes made were dated after Transporter 2 received the materials. Although the manifests read "Change OK per Charles Rivera", the changes were not completed by Daniels Sharpsmart personnel, but off-site by "BP".

4. The contingency plan contained references to an inaccurate fire department for contact during an emergency.

Explanation (FLDEP): The contingency plan must describe arrangements agreed to by local police departments, fire departments, hospitals, contractors, and State and local emergency response teams to coordinate emergency services, pursuant to §265.37. Specifically, Daniel's Sharpsmart referenced a fire station in the contingency plan that was not in the same county as the transfer facility.

Response: The Daniels Sharpsmart, Inc. Contingency Plan was prepared in accordance with 40 C.F.R. Part 265 (as adopted by reference in paragraph 62-730.171(4)(a), F.A.C.). The designated Fire Department listed within the submitted contingency plan was Kissimmee Fire Department, less than 10 miles away. A copy of the contingency plan was submitted to this local fire department and applicable arrangements made. However, in an email from John White dated 6/1/20, he stated there was a closer Fire Department in Orange County, less than 3 miles away. Daniels updated the Contingency Plan on 6/2/20 to reference the Orange County Fire Station #73 providing receipt of submission and applicable arrangements.

The above referenced regulation does not directly specify that using a Fire Department in another county is prohibited or one which must be selected within a certain distance. Assuming the Kissimmee Fire Department may be defined as local (as not all Fire Departments are within the same counties as hazardous waste facilities), was the reasoning for the designation. Daniels understands the importance of ensuring the Contingency Plan is accurate and thanked John for bringing this to our attention.



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5. Changes were made to manifests without the generator's knowledge or approval.

Explanation (FLDEP): It is unlawful for any hazardous waste generator, transporter, or facility owner or operator to knowingly make any false statement, representation, or certification in any application, record, report, plan, or other document filed or required to be maintained pursuant to the provisions of this act; Three exception reports provided to the Department by hazardous waste generators indicate changes have been made to manifests, after the manifests were signed and certified by the generator as accurate. The changes were made by Daniel's SharpSmart personnel without the knowledge or approval of the generator(s).

Response:

Daniels SharpSmart is continuously growing to be a leader in healthcare waste management because of our very mission, To Make Healthcare Safer. We as a partner to healthcare facilities understand that this can not be accomplished and runs parallel to operating within compliance of all applicable regulation. The changes that were made to the manifests as explained through this response letter were not done maliciously and did not intend to make any false statements. As described, for Manifest Discrepancy Report – Manifest# 000973721WAS & 001059213WAS, it was determined the manifests were misplaced by the Daniels driver. When it was identified the manifests were missing, the containers were transferred to another manifest to ensure accountability. Regarding Manifest Discrepancy Report - Manifest 001059154WAS, Transporter 2 signed acknowledging the receipt of the materials on the accompanying manifests from the Daniels Orlando 10-day Facility. Changes made were dated after Transporter 2 received the materials. Although the manifests read "Change OK per Charles Rivera", the changes were not completed by Daniels SharpSmart personnel, but off-site by "BP". However, of course, any changes made to the hazardous waste manifest must be approved by the generator first.

Corrective action has already been taken with the drivers responsible for misplacing the two manifests and personnel editing manifests without first confirming with the generator. Additionally, Daniels and AdventHealth hospital system had a meeting dated 8/6/20, coming together to discuss hazardous waste manifesting. Should a hazardous waste generator not receive a return copy of the manifest with the designated facility owner/operator signature, exception reporting requirements in accordance with 40

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CFR 262.42 must be followed. Established contacts with the generator will connect with Management at the Daniels Orlando 10-day Facility to communicate the issue. Daniels Orlando Mgt. and Daniels Chicago C, H&S will work together in partnership with Heritage Environmental to resolve. Daniels will also ensure to alert the generator of any possible edits required to the hazardous waste manifest before they are made. If corrections are not approved/verified before 10-Day limit, waste will be returned to the generator.

6. The 10-day transfer facility log was incomplete and inaccurate.

Explanation (FLDEP): The transfer facility shall maintain a written record of the items listed below. This recordkeeping requirement applies to all hazardous waste that enters and leaves the transfer facility, including hazardous waste generated by very small quantity generators (VSQGs). The record needs to include the manifest number or shipping paper number, the date when waste enters and leaves the facility, generator's name and EPA/DEP identification (ID) number, for VSQGs without an EPA ID number, the name and address of the generator, amounts of hazardous waste and EPA waste codes. The 10-day transfer log provided by Daniel's SharpSmart failed to include the following information: the date the waste left the facility, the generator's name and EPA/DEP ID number, and the hazardous waste code(s) associated with each shipment.

Response:

As response to John White's 4/7/20 email requesting the 10-day log meeting the requirements F.A.C. 62-730.171(6), Daniels had forwarded an example log for a random week in January 2020. The format of the log that was submitted to the Department was missing columns for Generator's Name and EPA/DEP ID number and hazardous waste code(s) associated with each shipment. A column heading for date the waste left the facility was existent, however, not completed. The log was also not signed or certified by any Daniels operator and therefore should not have been forwarded to the Department. This log was incorrect and did not realize so until John White brought it to our attention on 4/29/20.

A subsequent email followed on 5/14/20 with the correct manifest format for 6+ months of waste transferred through the Facility. This was the correct manifest log the Facility should have initially submitted.



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Daniels provides healthcare waste services consistent with the Department's approach, focusing on safety, compliance, and environmental sustainability. We sincerely appreciate the Department's collaboration, value our relationship, and continue to welcome further discussion should it be required regarding this matter.

Should you have any questions or require anything further please feel free to connect at any time.

Sincerely,

Kyle Little
Daniels Sharpsmart, Inc. | USA
Compliance Manager



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