

InterOffice Memorandum

CENTRAL DISTRICT

TO: Stericycle Specialty Waste Solutions, Inc. File
Orange County - HW

FROM: John White
Environmental Specialist

DATE: 09/30/2011

SUBJECT: Informal Meeting

On September 30, 2011, John White and Janine Kraemer, Florida Department of Environmental Protection met with TJ McCaustland, Stericycle Specialty Waste Solutions, Inc. (SSWSI) to discuss the Department's settlement offer, dated September 20, 2011.

SSWSI provided a written response to the Department's offer and wanted to discuss issues with Physician Sales and Service's (PSS) quarantine log, which was used to identify potential waste items shipped off-site by the facility.

The Department indicated that the types and volumes of waste being shipped from PSS in 2011 are significantly different from those in 2008-2010. The facility is now managing their waste properly, which was not happening before the inspection in January 2011.

The Department discussed its options for resolving this case, through a consent order or through filing a civil suit. Stericycle was asked to meet with Orange County representatives to determine how settlement of the enforcement case would affect the permitting for the biological waste incinerator on Keene Road, Apopka, Florida, and get back with us within 30 days.

jw



Rick Scott
Governor

Jennifer Carroll
Lt. Governor

Herschel T. Vinyard, Jr.
Secretary

Facility name

Type of meeting

Date _____

[illegible]



September 30, 2011

VIA ELECTRONIC DELIVERY

John White
Hazardous Waste Section, Central District
Florida Department of Environmental Protection
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

**RE: STERICYCLE SPECIALTY WASTE SOLUTIONS
WARNING LETTER (OCD-HW-11-256)
HAZARDOUS WASTE FACILITY ID# FLR000006353**

Dear Mr. White

Stericycle Specialty Waste Solutions, Inc. (SSWSI) is in receipt of the Warning Letter OCD-HW-11-256 and settlement offer from the Florida Department of Environmental Protection (the Department) dated September 20, 2011. SSWSI does not find the Department's offer acceptable and would like to share with the department the information we have concerning the case. The evidence shows that the Department's comments and violations are based on misinformation and conjecture that there was intentional treatment of hazardous waste at our medical waste facility.

In a letter dated July 26, 2011 the Department requested Physician Sales & Service (PSS) provide information regarding the disposal of hazardous waste chemicals identified on the facilities quarantine log/disposal log that were not found on hazardous waste manifests. PSS provided the Department with documentation, however it was neither accurate nor complete and it is SSWSI's position that this is the cause of the misinformation. Comprehensive review of the PSS quarantine logs show that this was intended to be a general log not as an accurate shipping list. SSWSI respectfully refutes the accuracy of the information provided by PSS to the Department.

SSWSI suggests that PSS provided DEP with quarantine logs without adequate explanation on the process for creating and using these logs. The items on a quarantine log may be shipped for destruction, returned to the manufacturer for credit, held for sample retention or similar activities, or returned to distribution inventory. Ultimately, a quarantine log is really used to remove items from a distributor's inventory available for shipment, not a waste inventory. PSS did not present these logs to SSWSI as an inventory of the items presented for waste shipment, but rather as supporting documentation. SSWSI reviewed quarantine logs to assist in the segregation of waste but did not rely on the quarantine log to create manifests or packing lists. Historically, these have not been a fully accurate account of the waste being provided.

Additionally review of PSS quarantine logs further shows that did not even accurately reflect the end disposal facility for disposal; rather that Stericycle removed the material. Attached you will

find Appendix A an example of the PSS quarantine log discussed. Documentation shows that some items, such as sterile water as being shipped as hazardous waste, while ethyl chloride is documented as shipped as non-hazardous to Stericycle. Properly prepared shipping documents and packing lists show the ethyl chloride was in fact properly shipped as hazardous waste to a permitted RCRA TSD.

SSWSI has reconciled quarantine logs to inventory items presented for destruction and has found repeated instances of discrepancies, such as the one above. As recently as June 2011, quarantine lists were provided with inconsistencies. On June 7, 2011, a quarantine list was provided that listed 456 items. A line by line reconciliation revealed that only 157 items were presented for shipment (34%). On June 24, 2011, a quarantine list with 190 items was presented of which 186 items were present (97.8%). Attached is a spreadsheet with analysis as to the accuracy of the quarantine logs as waste inventory. (Appendix B)

SSWSI has reviewed all of the shipments from PSS for 2011 and identified in some cases there were overages and in some cases a shortage of waste when compared with the quarantine log. Below is a table demonstrating this reconciliation of the discrepancies the Department addressed in the original warning letter **OWL-HW-11-013** that SSWSI responded to on July 15, 2011.

To summarize the materials the Department was seeking that were identified as "Items not presented for shipment" in the July 15, 2011 response:

Fluvirin SRY 2010/2011	36	Item not presented to SSWSI for shipment
Tetanus Tox PF SDV 10X.5ML	4	Item not presented to SSWSI for shipment
Histofreezer 36-72KT-2/5ML	1	Item not presented to SSWSI for shipment
Decavac Tetanus	1	Item not presented to SSWSI for shipment
Fluvirin 5ML 2010/2011	17	Item not presented to SSWSI for shipment
Histofreezer 170ML 2/5MM MIX	1	Item not presented to SSWSI for shipment
Phenytoin Sod 50MG/ML VL	1	Item not presented to SSWSI for shipment
Silvadene Crm 20GM	3	Item not presented to SSWSI for shipment
Topex Anesth Spy Cherry 2OZ	1	Item not presented to SSWSI for shipment

Subsequent to the Department's inquiries the following shipments occurred with quarantine logs presented:

On April 8, 2011 SSWSI shipped from PSS on hazardous waste manifest 007950583JJK the following items:

2 Histofreezer

The PSS Quarantine Log shows 1 Histofreezer

Every item was reconciled for a discrepancy of 1 extra Histofreezer

On May 20, 2011 SSWSI shipped from PSS on hazardous waste manifest 007953809JJK the following items:

1 Histofreezer

24 Adacel TDAP Vac SYR 5X.5ML

20 Tetanus Tox PF SDV 10X .5ML

20 Gardasil Vaccine SDV 0.5ML

24 Fluvirin SRY 2010/2011
10 Havrix 720ELU SDV PF 10/BX

The PSS Quarantine Log shows:

1 Histofreezer
2 Adacel TDAP Vac SYR 5X.5ML
11 Tetanus Tox PF SDV 10X .5ML
2 Gardasil Vaccine SDV 0.5ML
12 Fluvirin SRY 2010/2011
2 Havrix 720ELU SDV PF 10/BX

Every item was reconciled for a discrepancy of:

22 extra Adacel TDAP Vac SYR 5X.5ML
9 extra Tetanus Tox PF SDV 10X .5ML
18 extra Gardasil Vaccine SDV 0.5ML
12 extra Fluvirin SRY 2010/2011
8 extra Havrix 720ELU SDV PF 10/BX

On June 10, 2011 SSWSI shipped from PSS on hazardous waste manifest 008116342JJK the following items:

1 Fluvirin SYR L/L 2010/2011
10 Tetanus Tox PF SDV 10X .5ML
1 Duoned Inh sol Vaccine

The PSS Quarantine Log shows:

13 Fluvirin
3 Tetanus Tox
0 Duaneb

Every item was reconciled for a discrepancy of:

12 missing Fluvirin
7 extra Tetanus Tox
1 Duoneb

On June 30, 2011 SSWSI shipped from PSS on hazardous waste manifest 008110284JJK the following items:

10 Solu Medrol 40MG PF VL 1ML
10 Tetanus Tox PF SDV 10X
10 Decavac PF (Tetanus)
10 Adacel TDAP Vac SYR 5X.5ML
1 Hydroxyzine HCl

The PSS Quarantine Log shows:

1 Solu Medrol 40MG PF VL 1ML
0 Tetanus Tox PF SDV 10X
0 Decavac PF (Tetanus)

2 Adacel TDAP Vac SYR 5X.5ML
5 Hydroxyzine HCl

Every item was reconciled for a discrepancy of:

9 extra Solu Medrol 40MG PF VL 1ML
10 extra Tetanus Tox PF SDV 10X
10 extra Decavac PF (Tetanus)
8 extra Adacel TDAP Vac SYR 5X.5ML
4 missing Hydroxyzine HCl

To summarize the discrepancies of the quarantine logs and manifests of 2011:

01 extra Histofreezer
30 extra Adacel TDAP Vac SYR 5X.5ML
26 extra Tetanus Tox PF SDV 10X .5ML
18 extra Gardasil Vaccine SDV 0.5ML
08 extra Havrix 720ELU SDV PF 10/BX.
01 extra Duoneb.
09 extra Solu Medrol 40MG PF VL 1ML
10 extra Decavac PF (Tetanus)
12 extra Fluvirin SRY 2010/2011 and 12 missing Fluvirin for a net of 0

Reconciling the discrepancies with **Items not presented to SSWSI for shipment** in the July 15, 2011 response:

NET DIFFERENCE OF ITEMS SHIPPED:

-17 Fluvirin 5ML 2010/2011
-36 Fluvirin SRY 2010/2011
22 Tetanus Tox PF SDV 10X.5ML
-1 Histofreezer 36-72KT-2/5ML
9 Decavac Tetanus
0 Histofreezer 170ML 2/5MM MIX
-1 Phenytoin Sod 50MG/ML VL
-3 Silvadene Crm 20GM
-1 Topex Anesth Spy Cherry 2OZ
18 Gardasil Vaccine SDV 0.5ML
30 Adacel TDAP Vac SYR 5X.5ML
08 Havrix 720ELU SDV PF 10/BX.
01 Duoneb
09 Solu Medrol 40MG PF VL 1ML

38 more items shipped as hazardous waste than represented on PSS Quarantine Logs

When studying vaccines and mercury shipped by PSS as well as items identified by the department there are 59 items missing while there were 97 items shipped that were not identified on a quarantine log. The missing items could be misidentified on the quarantine log and have been shipped for hazardous waste destruction but not described on the log correctly. SSWSI packed what was presented for shipment and manifested accordingly. Due to the discrepancies

identified on the PSS quarantine logs it is SSWSI's position that no hazardous waste was shipped to a non-permitted facility. Without a complete physical inventory of the PSS warehouse and a reconciliation of all shipping records, including Reverse Distribution Returns, and Manufacturer Recall Returns, it is not possible to accurately reconcile the PSS inventory. It is evident that PSS does not always accurately reconcile their quarantine log. It is also possible that the missing items are still in the PSS warehouse and have not been shipped anywhere.

PSS has a responsibility to sign the shipping documents taking accountability for assuring the information presented on the manifest is true and accurate. The quarantine log is not a binding legal document. Manifests documents prepared by SSWSI were accurate and true

In conclusion, Stericycle Specialty Waste Solutions, Inc. believes that all hazardous waste SSWSI transported from PSS was properly identified and shipped to the appropriately permitted facility accepting hazardous waste and that no hazardous waste was shipped to Stericycle's Keene Road incineration facility in Apopka, Florida. SSWSI will continue to be diligent in properly managing all wastes. We respectfully request that this portion of the violations be retracted.

Thank you for your time and attention, and if additional information is required, please feel free to contact Mr. TJ McCaustland at 770. 891.2531 via email at tmccaustland@stericycle.com, or me a 612.285.9865 via email at wscheel@stericycle.com.

Sincerely,

Wade Scheel

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