
October 19, 2016

Maggie Johnson
San Francisco Department of the Environment
1455 Market Street, Suite 1200
San Francisco, CA 94103
safemeds@sfgov.org

Re: Request for Approval of MED-Project Plan Modifications

Dear Ms. Johnson:

San Francisco MED-Project LLC (“MED-Project”) requests the San Francisco Department of the Environment’s (the “Department’s”) approval to modify the MED-Project Product Stewardship Plan’s (“MED-Project Plan’s” or “the Plan’s”) collection process, transporter and disposal facility for Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events.¹ As discussed with the Director on September 7, 2016, MED-Project expects that these changes will accelerate kiosk drop-off site collection by allowing MED-Project to use existing United Parcel Service (“UPS”) transportation networks and securely store unwanted medicine in the event of a disposal facility shutdown.

Process for Material and Non-Material Modifications to an Approved Plan

To modify an approved Plan, a producer or group of producers must submit a written request to the Director and provide a Review Fee. Ordinance § 2212. Proposed changes to an approved Stewardship Plan that substantively alter plan operations, including, but not limited to, changes to participating Manufacturers, collection methods, achievement of the service convenience goal, policies and procedures for handling Unwanted Covered Drugs, or education and promotion methods or disposal facilities, must be approved in writing by the Director before the changes are implemented. *Id.* The plan operator of an approved Stewardship Plan shall notify the Director at least 15 days before implementing any changes to drop-off site locations, methods for scheduling and locating periodic collection events, or methods for distributing prepaid, preaddressed mailers, that do not substantively alter achievement of the service convenience goal under Ordinance § 2205(c) or other changes that do not substantively alter plan operations. *Id.*

Request to Modify the Plan’s Unwanted Medicine Collection Process

MED-Project seeks to amend the Plan’s collection process in Plan Sections VI(B)4, VI(B)5, and VI(C)2.

¹ The terms “MED-Project Plan” and “Plan” in this letter refer to the Plan MED-Project submitted on July 14, 2016.

The Plan approved on July 25, 2016 provided that two Stericycle, Inc. (“Stericycle”) employees would service Kiosk Drop-Off Sites. These two employees would work with the United States Drug Enforcement Administration (“DEA”) registrant to remove inner liners, package the inner liner, and transport the Unwanted Medicine directly to the disposal facility. This approved Plan also provided that Stericycle employees would package Unwanted Medicine collected at Take-Back Events and transport this Unwanted Medicine directly to the disposal facility.

MED-Project now proposes to amend the July 14, 2016 Plan so that one Stericycle employee shall package the Unwanted Medicine collected at Kiosk Drop-Off Sites, schedule a pickup of the Unwanted Medicine from the Kiosk Drop-Off Sites by UPS, and leave the prepared shipment of packaged Unwanted Medicine at the Kiosk Drop-Off Site for storage until the scheduled pickup. At Take-Back Events, Stericycle employees shall package the collected Unwanted Medicine and schedule UPS pickup at the overseeing LEA’s physical location. The packaged Unwanted Medicine shall then be transported under the supervision of the LEA to the LEA’s physical location for storage until the scheduled UPS pickup.

The UPS pickup shall take place based on the regularly scheduled service for the local area following the kiosk service or Take-Back Event. Stericycle will be the offeror of the shipment.

Request to Modify the Plan’s Transporter and Disposal Facility

MED-Project seeks to amend the Plan’s transporter and disposal facility in Plan Sections XI(A) and XI(B).

The Plan approved on July 25, 2016 provided that Stericycle would transport all collected Unwanted Medicine directly to a Clean Harbors hazardous waste facility in Wendover, Utah. MED-Project now proposes to amend the Plan to send all collected Unwanted Medicine via common carrier to the Stericycle facility in Indianapolis, Indiana. From there, using Heritage Transport, the Unwanted Medicine is transported to the Heritage Thermal Services permitted hazardous waste facility in East Liverpool, Ohio. The Heritage Thermal Services facility is a hazardous waste facility with all applicable permits. *See* Attachment 1. Thus, it satisfies the requirements for a disposal facility in Ordinance Section 2207(A), which requires that a disposal facility must be “a permitted hazardous waste disposal facility as defined by the United States Environmental Protection Agency 20 under 40 C.F.R. parts 264 and 265.” Ordinance § 2207(A).

All information the San Francisco Safe Drug Disposal Stewardship Ordinance require is provided in Attachments 1, 2, and 5.

Additionally, MED-Project seeks to add Stericycle facility in Indianapolis, Indiana to the Plan. UPS will deliver all Unwanted Medicine shipped from Kiosk Drop-Off Sites and Take-Back Events to this facility. The Unwanted Medicine shall be stored in accordance with DEA

requirements until transport to the disposal facility identified in Attachment 1.² Permit information for the Stericycle, Inc. Indianapolis Facility and Heritage

Transport is provided in Attachments 3, 4, and 6. Attachment 7 provides a flow chart outlining the process proposed in this modification request.

At this time, MED-Project is not proposing a second transportation vendor or disposal facility. The common carrier model affords Stericycle flexibility when transporting collected material to the disposal facility (subject to the 30 day destruction requirement in 21 C.F.R. § 1317.15(d)). Under the originally proposed “milk-run” collection model, DEA requirements obligated two Stericycle employees to transport collected material “directly to the registered location.” *See, e.g.,* 21 C.F.R. § 1317.95(b). If the approved disposal facility had an emergency shutdown, a second vendor was helpful under the “milk-run” collection model to ensure prompt disposal in the event two Stericycle employees were not immediately available to transport the collected material when the disposal facility re-opened. A second disposal facility also helped ensure prompt disposal of collected material in the event of disposal facility shutdowns. The common carrier model reduces the need for a second vendor or disposal facility. Instead of transporting collected material directly to the disposal facility, Stericycle can temporarily consolidate collected material at its Indianapolis facility and then schedule transport to Heritage Thermal Services around any temporary disposal facility closures or other conflicts.

Conclusion

As the collection process, transporters, and disposal facility satisfy all applicable requirements, this modification request should be approved. Please let MED-Project know if you have any questions about the request to modify the Plan’s Unwanted Medicine collection process, transporters, and disposal facility.

Sincerely,



Dr. Victoria Travis, PharmD, MBA
National Program Director

Attachments

² While Heritage Transport is a DEA registrant, Stericycle does not transfer ownership of the Unwanted Medicine to Heritage Transport. For this reason, two Stericycle employees witness incineration of the Unwanted Medicine.

Attachment 1: Heritage Thermal Services – Ohio Facility

The following will be added to Plan Section IX(B), replacing the existing disposal facility information.

Name: Heritage Thermal Services – Ohio

Addresses: 1250 Saint George Street, East Liverpool, Ohio, 43920

Phone: 800-545-7655

Website: <http://www.heritage-thermal.com/>

Type: Permitted Hazardous Waste Incinerator

DEA Registration No.: RH0387628

RCRA Permit No: OHD980613541

Permit Status: Active

Penalty Record (5 years): See Attachment 5

How will this facility be used: This facility will be utilized to incinerate Unwanted Medicine recovered from Kiosk Drop-Off Sites and Take-Back Events.

Attachment 2: United Parcel Service

The following will be added to Plan Section XI(A), replacing the existing transporter information.

Name: United Parcel Service
Address: 55 Glenlake Parkway NE, Atlanta, GA, 30328
Phone: 800-PICK-UPS
Website: www.UPS.com/
Type: Logistics Company
U.S. Small Package DOT number: 21800
U.S. Freight DOT number: 121058

Permit Status: All relevant permits are active and in good standing. Available upon request.

Penalty Record: For enforcement history UPS advises that “all material government investigation and enforcement activity is provided in our SEC filings at www.investors.ups.com”

How will this transporter be used: UPS will transport Unwanted Medicine to the Stericycle, Inc. Indianapolis, Indiana facility.

Attachment 3: Stericycle, Inc., Indianapolis, Indiana Facility

The following will be added to Plan Section XI, becoming a new subsection.

Name: Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)

Addresses: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901

Phone: 317-275-7530

Website: www.stericycleenvironmental.com

Type: DEA-compliant and registered collector facility

DEA Registration No.: RS0331607

RCRA Permit No: INR000110197

Permit Status:

- i. A Hazardous Waste: RCRA Part B. Permit Number: INR00010197. Expiration: 1/7/2016 (submitted for renewal in July 2015, pending approval).
- ii. Solid Waste: Processing Facility. Permit Number: FP 49-57. Expiration: 8/3/2020.
- iii. Air Quality: Exempt. Permit Number: E097-28740-00671. Expiration: N/A.

Penalty Record (5 years): See Attachment 6

How will this facility be used: This facility will be utilized to accept delivery of Unwanted Medicine transported by UPS.

Attachment 4: Heritage Transport

The following will be added to Plan Section XI, becoming a new subsection.

Name: Heritage Transport
Address: 1626 Research Way, Indianapolis, IN 46231
Phone: (317) 486-2973
Website: <http://www.heritage-enviro.com/>
EPA ID#: IND 058 484 114
US DOT Number: 314460

Permit Status: All relevant permits are active and in good standing. Available upon request.

Penalty Record (5 years): None

How will this transporter be used: Heritage Transport will be the transporter utilized to transport Unwanted Medicine to a permitted hazardous waste incinerator from the Stericycle, Inc. Indianapolis, Indiana facility.

Attachment 5: Heritage Thermal Services – Ohio Facility Penalty Record

The following will be added to Plan Appendix L, becoming a new subsection.

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
Director's Final Findings & Orders	4/2/2015	1250 Saint George Street, East Liverpool, Ohio, 43920	Ohio EPA DAPC and DMWM	Close the NOVs issued to HTS due to the 7/13/13 Incident: Dust Nuisance (DAPC) Unlawful disposal of hazardous waste and improper maintenance and operation of equipment (DMWM)	\$34,000	HTS is in discussions with Ohio EPA
Finding of Violation	3/25/2015	1250 Saint George Street, East Liverpool, Ohio, 43920	US EPA	HTS exceeded MACT and Title V OPLs on several occasions.	TBD	HTS is in discussions with US EPA
NOV	9/16/2014	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of OAC 3745-55-75(b) Bulk waste container stored outside of secondary containment.	NA	Closed – RTC received in a letter dated December 8, 2014, September 16, 2014 letter acknowledged that issue had been corrected on date of inspection.
NOV	9/16/2014	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of OAC 3745-54-15(c) Immediate action had not been taken to prevent further incident following discovery of equipment damage.	NA	Closed – RTC received in a letter dated December 8, 2014, September 16, 2014 letter acknowledged that issue had been corrected on date of inspection.

NOV	9/16/2014	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of Permit Condition C.6(c) Spills not cleaned up in a timely manner.	NA	Closed – RTC received in a letter dated December 8, 2014, September 16, 2014 letter acknowledged that issue had been corrected on date of inspection.
NOV	10/2/2013	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Ash release on 7/13/13 was an unlawful Disposal of Hazardous Waste; and failure of proper Operation and Maintenance of equipment/facility	NA	HTS responded in a letter dated October 21, 2013. HTS met with OEPA on 9/22/14 to provide update. HTS provided written update and request for RTC in letter dated 10/17/14. HTS 2 nd request for RTC in letter dated 12/12/14. HTS 3 rd request for TRC in letter dated 2/3/2015. HTS has completed requirements for RTC and is actively pushing OEPA for TRC.

NOV	8/5/13	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	Ash release determined to be a public nuisance in violation of OAC 3745-15-07	NA	HTS responded in a letter dated August 22, 2013. HTS met with OEPA on 9/22/14 to provide update. HTS provided written update and request for RTC in letter dated 10/17/14. HTS 2 nd request for RTC in letter dated 12/12/14. HTS 3 rd request for RTC in letter dated 2/3/2015. HTS has completed requirements of RTC and is actively pushing OEPA for RTC.
NOV	6/21/2013	1250 Saint George Street, East Liverpool, Ohio, 43920	OSHA	Violation of various standards – decontamination, improper storage of water reactives, not identifying hazards.	\$11,802	Closed – HTS settled this matter on 8/30/13. HTS and OSHA met for informal conference on 7/16/13. Agreement reached – citation 4 vacated, instances a and c for citation 3 vacated; rewording of citation 1 and 2. Penalty reduced to \$11,802.
NOV/RTC	1/9/2013	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of Section F-5 following policy and procedures – no grounding of container that caught fire.	NA	Closed – NOV and RTC in the same letter (dated 1/7/13).

NOV	9/7/2012	1250 Saint George Street, East Liverpool, Ohio, 43920	OSHA	Violation of OSHA standards Training; permits; emergency response; general duty; guarding openings; confined space.	\$31,500 reduced to \$17,010	Closed – HTS settled this matter on 10/15/12. WTI and OSHA met for an informal conference on 9/27/12. WTI settled at the informal Settlement conference on 9/27/12.
NOV	8/6/2012	1250 Saint George Street, East Liverpool, Ohio, 43920	OSHA	Violation of various portions of the PSM standard – 29 CFR 1910.119	\$63,000	Closed – HTS settled this matter 6/13/14. WTI and OSHA met for an informal conference on 8/21/12. WTI expected to contest citation. Letter of Contest. Met with OSHA for Formal Settlement conference – no settlement reached. Case is set to go to AL Judge on 1/23/13. Final Agreement was signed 5/13/13 and official date is June 13, 2013.
NOV	6/12/2012	1250 Saint George Street, East Liverpool, Ohio, 43920	OSHA	Violation of OSHA standards Training; permits; emergency response; general duty; guarding openings; confined space.	\$21,420	Closed – HTS settled this matter on 4/11/13. WTI and OSHA met for an informal conference on 6/28/12. Informal settlement declined by WTI; Letter of Contest sent 7/6/12. WTI met at Formal Settlement hearing on 12/18/12 in effort to settle. HWTI formal settlement on 2/19/13. OSHRCT approved.

NOV	4/30/12	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of Section F – Permittee ensure employees are protected by requiring use of PPE. Violation of Section H – WTI has training program to ensure employees are properly trained. Violation of OAC 3745-54-15 (A)(2) and (B)(4) – Prevent damage to human health through inspections and corrections.	NA	Closed – RTC was issued 8/10/12. WTI responded in a letter dated 5/22/12.
NOV	3/15/12	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of permit condition B.1 – Design and operation (as spill not cleaned up) and permit condition B.5 General Inspection – hazardous waste collection container not properly labeled or closed (hopper in slag/ash area).	NA	Closed – RTC was issued 8/6/12. 3/30/12 email acknowledges WTI has met requirements for TRC. 4/17/12 WTI submits letter to get RTC.
NOV	12/6/11	1250 Saint George Street, East Liverpool, Ohio, 43920	DMWM	Violation of permit conditions B.1(e) and B.3(b) – incineration of inorganic metal bearing waste (40 CFR 268.3) (self report).	NA	Closed – RTC was received in the NOV letter (12/6/11).
NOV	6/3/11	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	WTI was above its short term limit for NOx, SO ₂ , and THC.	NA	Closed – OEPA approved new averaging period. HTS is working with OEPA on modifying emission averaging time.

NOV	3/29/11	1250 Saint George Street, East Liverpool, Ohio, 43920	DHWM	Violation of permit conditions B.1(e) and B.3(b) – incineration of inorganic metal bearing waste (40 CFR 268.3) (self report)	NA	Closed – RTC was received in the NOV letter (3/29/11)
NOV	2/15/11	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	WTI was above its short term limit for NOx and THC.	NA	Closed – OEPA approved new averaging period. HTS is working with OEPA on modifying emission averaging time.
Complaint	12/22/10	1250 Saint George Street, East Liverpool, Ohio, 43920	US EPA	WTI did not meet the HWC MACT emission standards for Mercury and Dioxin/Furans during the CPT (violation of the facility PTI and Title V permit).	\$92,500	Closed – This issue was resolved 10/6/11. WTI requested a hearing with US EPA to discuss in letter dated 1/26/11. Met with US EPA in March 2011; penalty was reduced with a SEP. SEP completion report submitted 10/6/11.
NOV	11/23/10	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	WTI was above its short term limit for SO ₂ , NOx, and THC.	NA	Closed – OEPA approved new averaging period. HTS is working with OEPA on modifying emission averaging time.
NOV	8/3/10	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	WTI was above its short term limit for SO ₂ , NOx, opacity, and THC.	NA	Closed – OEPA approved new averaging period. HTS is working with OEPA on modifying emission averaging time

NOV	6/23/10	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	WTI did not meet the HWC MACT emission standards for Mercury and Dioxin/Furans during the CPT (violation of the facility PTI and Title V permit).	NA	Closed – No response required.
FOV	6/18/10	1250 Saint George Street, East Liverpool, Ohio, 43920	US EPA	WTI did not meet the HWC MACT emission standards for Mercury and Dioxin/Furans during the CPT (violation of the facility PTI and Title V permit).	See 12/22/10 entry	Closed – This issue was resolved 10/6/11.
NOV	6/14/10	1250 Saint George Street, East Liverpool, Ohio, 43920	DAPC	WTI was above its short term limit for SO ₂ , NO _x , and THC.	NA	Closed – OEPA approved new averaging period. HTS is working with OEPA on modifying emission averaging time.

Attachment 6: Stericycle, Inc., Indianapolis, Indiana Facility

The following will be added to Plan Appendix L, becoming a new subsection.

Type	Date	Address	Regulatory Body/Agency	Description of Alleged Violation
Disposal Facility	6/23/2015	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	6/26/2014	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	3/26/2014	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	6/28/2013	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	12/11/2012	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	4/23/2012	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	4/21/2011	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.

Attachment 7: Process Flow Chart

The following is a flow chart outlining the updated process proposed in this modification request.

