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May 16, 2016

Associate Administrator for  
Hazardous Materials Safety  
Pipeline & Hazardous Material  
Safety Administration  
U.S. Department of Transportation  
1200 New Jersey Avenue, S.E.  
East Building, 2<sup>nd</sup> Floor (PHH)  
Washington, DC 20590  
Att: General Approvals & Permits,  
PHH-31

Chief, Hazardous Materials Division  
Federal Motor Carrier Safety Admin.  
U.S. Dept. of Transportation  
Washington, D.C. 20590-0001

Re: Emergency Petition for Special Permit Under 49 C.F.R. Subpart B  
Stericycle Specialty Waste Solutions, Inc.

**REQUEST FOR SPECIAL PERMIT PURSUANT TO  
49 C.F.R. § 107.105**

Stericycle Specialty Waste Solutions, Inc. ("Stericycle") hereby requests the Pipeline & Hazardous Material Safety Administration of the U.S. Department of Transportation grant it a special permit, on an emergency basis, exempting it from various provisions of the Hazardous Materials Regulations ("HMRs") for transportation of certain specific hazardous materials in connection with pharmaceutical take-back programs as described herein.

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Detroit • Spokane • Dallas/Fort Worth • Milwaukee • Philadelphia/Mt. Ephraim

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***Applicant information***

1. Stericycle maintains its principal place of business at 2850 100<sup>th</sup> Ct. NE, Minneapolis, MN 55449.
2. Stericycle's point of contact for this special permit application is Wade Scheel, Director of Environmental, Health & Safety (Phone: 612-285-9865; Email: WScheel@stericycle.com).
3. Stericycle handles the disposal and transportation of waste material, including hazardous waste, non-hazardous waste, and universal waste, for its various retail customers throughout the United States, including, for example, Target, Walmart, CVS and Walgreens.
4. Stericycle is registered as a motor carrier with the Federal Motor Carrier Safety Administration under USDOT Number 1348411.

***Company President and DUNS identifier***

5. Charles A. Alutto is the President and CEO of Stericycle.
6. Stericycle's DUNS identifier is 008040649.

***Request for Emergency Processing under 49 C.F.R. § 107.117***

7. Stericycle respectfully requests this application be processed under the emergency processing regulations set forth in 49 C.F.R. § 107.117. Emergency processing is necessary in this case for immediate national security and public health reasons. More specifically, opiate abuse in the U.S. has become a growing national public health concern that has resulted in regulatory enhancements by the U.S. Drug Enforcement Administration ("DEA") to facilitate pharmaceutical take-back programs throughout the U.S. with the participation of various retail pharmacies. Working in conjunction with the DEA and its retail pharmaceutical customers, Stericycle is involved in ensuring the safe transportation and disposal of controlled substances that are being collected at the various take-back locations, which will benefit national security and the public health by removing opiates and other harmful controlled substances from illegal use. A special permit, however, is needed to safely and efficiently allow Stericycle to effectuate the transportation of controlled substances received through the DEA take-back programs to Stericycle's designated Transportation, Storage, and Treatment facilities ("TSDF").

### ***Locations where special permit will be used***

8. The precise locations where this special permit will be used are unknown at this time. Stericycle anticipates it will be used at the locations of the retail pharmacies that engage Stericycle to pick-up and dispose of pharmaceutical waste products as part of their pharmaceutical take-back programs, implemented in accordance with the U.S. Drug Enforcement Administration's ("DEA") Disposal of Controlled Substances Final Rule. See 79 Fed. Reg. 53,520 (Sept. 9, 2014). These pharmacies, which include, but are not limited to, CVS, Walgreens, Target, and Walmart, maintain retail locations across the country. As discussed below, pharmaceutical take-back kiosks may also be located at other controlled locations such as police departments or governmental office buildings.

### ***Special permit proposal***

9. Description of proposed special permit:
- a) In September of 2014, the DEA commenced its Disposal of Controlled Substances program, which implements the Secure and Responsible Drug Disposal Act of 2010 by "expanding options available to collect controlled substances from ultimate users for the purpose of disposal, including: Take-back events, mail-back programs, and collection receptacle locations." In essence, the rule authorizes ultimate users to transfer unwanted and unused pharmaceutical controlled substances to an authorized collector for safe, secure, and responsible disposal. It also establishes stringent requirements related to each element of the disposal process including the transfer, delivery, collection, destruction, return, and recall of the pharmaceuticals.
  - b) According to the DEA's Final Rule, once controlled substances have been collected from the ultimate users (at a collection receptacle or otherwise), the rule prohibits *anyone* from counting, sorting, inventorying, or otherwise individually handling the collected substances. See *id.* at 53,568 (discussing § 1317.75). In addition, the rule provides that "[c]ontrolled and non-controlled substances may be collected together and be comingled." *Id.* The rule then authorizes transportation companies to transport the collected substances for disposal, recognizing, however, that "[t]he DEA has been informed that if collected substances include hazardous materials, the

transportation of those materials is subject to all applicable DOT regulations, including the [HMR].” *Id.* at 53,554.

- c) Retail pharmacies across the country have, in accordance with the DEA’s Final Rule, begun implementing pharmaceutical take-back programs. A photograph of a representative take-back kiosk at a CVS/pharmacy is attached as Exhibit 1. They have also begun engaging companies like Stericycle transport and safely dispose of the pharmaceutical waste that they have collected.
- d) Because the DEA’s Final Rule expressly prohibits *anyone* from counting, sorting, inventorying, or otherwise individually handling the collected substances, it is impossible for companies like Stericycle to ascertain the contents of these packages, let alone sort, package, and mark them in accordance with the HMRs prior to transporting them for disposal.
- e) For this reason, Stericycle requests a special permit, exempting it from 49 C.F.R. Part 173, Subparts A through E, for shipments of hazardous materials made in accordance with the DEA’s Disposal of Controlled Substances program. In addition, Stericycle would request that it be allowed to classify the hazardous materials recovered through the DEA take-back program as either:

Medicine, liquid, flammable, toxic, n.o.s. (UN3248)  
Medicine, solid, toxic, n.o.s. (UN3249)

In doing so, Stericycle, consistent with the conditions set forth in the special permit and the applicable non-waived HMRs, could utilize the various exemptions for limited quantities contained in 49 C.F.R. § 172.315. Being able to handle the hazardous material product as a limited exemption and thus be exempt from the marking requirements (other than the marking required under § 172.315(a)(1)) allows compliance with the DEA regulations (21 C.F.R. § 1317.70(c)) specifying that, for security reasons, the package be nondescript and not include any markings or other information that may indicate the package contains controlled substances.

- 10. Package handling procedures (origin to destination):

- a) As a general matter, materials packaged under this special permit would consist of unused medications which have been accepted as part of public pharmaceutical waste take-back programs as authorized under DEA regulations. The unused medications are returned by individuals to a collection site and placed into a receptacle, such as a kiosk, which prevents unauthorized access. The kiosks are designed in a manner so that medications may be placed into the unit without actually opening the unit, but contents cannot be removed without the use of a key. The kiosks will be placed in controlled locations, such as retail pharmacies, police departments, or governmental office buildings, which allow for collection from the public to be continuous and unmanned.
- b) The kiosks are designed to have an inner receptacle with a plastic liner of no greater than 40 gallons. When it is time for the kiosk to be emptied, a waste service company technician and an employee or representative of the collection site, would jointly open the collection container. The technician will first ensure the integrity of the inner lining (verifying that there are no tears), and then goose-neck and zip-tie the liner closed and place the liner in a corrugated box or rigid plastic container conforming to the requirements of PG II or demonstrated equivalent not to exceed 40 gallons capacity. As noted, DEA regulations prohibit opening the inner liner once drugs are placed in the container.
- c) Each outer container would then be marked with the limited quantity markings required under § 172.315(a)(1), and tendered for transportation to a common or contract motor carrier (ground only) registered with the Federal Motor Carrier Safety Administration cosigned to be delivered to a properly permitted facility designated by Stericycle.

11. Packaging descriptions:

- a) The inner lining used in the kiosks will meet the minimum requirements of 21 C.F.R. § 1317.60, and 49 C.F.R. § 173.197(e)(1)(i) and (ii).
- b) The outer packaging will consist of a corrugated box or rigid plastic container conforming to the requirements under PG II or

demonstrated equivalent and no greater than 40 gallons capacity.

- c) The total weight of the inner and outer packaging and content shall not exceed 66 pounds or such other weight as may be restricted under the limited quantity exemption in 49 C.F.R. § 172.315.
- d) To ensure compliance with the DEA regulations in 21 C.F.R. § 1317.70(c), the packages would be exempt from any marking requirements, including any requirement to include the special permit number, other than the marking required by 49 C.F.R. §172.315(a)(1).

12. Operational Controls:

- a) All packages will be shipped via ground only.
- b) All packages will be prepared by Stericycle for shipment with a Stericycle trained technician performing all pre-transportation functions, including an inspection of the inner lining once removed from the kiosk to ensure its integrity prior to placement in the outer package. Any liner found to be damaged or leaking shall be over-packed into another liner without the removal of the contents of the initial liner, prior to being placed in the outer package.
- c) Stericycle will ensure compliance with the required closure instructions for the outer packaging.
- d) All packages will be tendered to an FMCSA-authorized common or contract motor carrier with signatures being required by the offeror to the carrier at pick-up and from the carrier to the consignee at the end properly permitted destination facility.
- e) The carrier will verify package compliance at the collection point prior to accepting the shipment to ensure the package is not leaking or damaged.

13. Though it is difficult to estimate with any amount of certainty (given that retail pharmacies are just now beginning to implement take-back programs), Stericycle estimates that the number of shipments that will move under the requested special permit per year is 12,000. This number can be

further broken down as follows: Approximately 1,000 locations serviced once per month. Stericycle also estimates that the quantity of pharmaceutical waste per package would be between 20 and 40 pounds, but in no event will the total weight of each box exceed 66 pounds.

14. Stericycle requests that the special permit be issued for an indefinite duration, to be periodically reviewed and renewed in accordance with the Agency's regulations.

### ***Certifications***

15. This special permit is not being sought in connection with a compliance review, inspection activity, or enforcement action.

16. Stericycle will act as a shipper under the terms of the proposed special permit.

17. Stericycle is registered under Subpart G of Part 107 under registration number 062915555018X (issued to Stericycle Specialty Waste). It is not required to be registered in accordance with Subpart F of Part 107 of Title 49 of the Code of Federal Regulations.

### ***Justification for Special Permit***

18. Stericycle believes that a special permit as described in this application is consistent with the public interest because, as noted, all shipments would be made pursuant to the DEA's Disposal of Controlled Substances program, the purpose of which is to "expand[] options available to collect controlled substances from ultimate users for the purpose of disposal, including: Take-back events, mail-back programs, and collection receptacle locations." As the DEA explained in its Final Rule, "[the DEA] has worked with the DOT to facilitate this process in an effort to ensure maximum participation in the collection of controlled substances for secure and responsible disposal . . . ." Without a special permit, companies like Stericycle could not legally transport these packages for disposal under the HMRs, which would frustrate Congress's clear intent in passing the Responsible Drug Disposal Act of 2010.

19. Stericycle also believes that a special permit as described in this application would achieve a level of safety at least equal to that required by the regulations because the shipments would be limited in quantity and would be securely packaged in inner liners and PG II outer packages not to exceed 66 pounds. The shipments would also be transported for immediate disposal, as authorized by the DEA's Final Rule.



20. PHMSA has issued similar special permits (SP-8445 & SP-16592), but SP-8445 currently excludes controlled substances from the relaxed marking requirements, and SP-16592 requires the hazardous material product to be placed in drums and be transported *by the grantee*. By simply expanding the previously-issued special permits to encompass controlled substances and expanded transportation options consistent with the existing limited quantity exemptions in the HMRs, Stericycle cannot identify any additional risks to the public, particularly since all such shipments would be subject to the DEA's Final Rule.

**WHEREFORE**, Petitioner Stericycle Specialty Waste Solutions, Inc., by counsel, respectfully requests the Pipeline & Hazardous Material Safety Administration grant it a special permit exempting its shipments made in accordance with the DEA's Disposal of Controlled Substance program from 49 C.F.R. Part 173, Subparts A through E.

Respectfully submitted,

*/s/ Timothy W. Wiseman*  
Attorney for Stericycle Specialty Waste  
Solutions, Inc.

Enclosure

4847-1743-9272, v. 1

# EXHIBIT 1

