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August 9, 2016

Mr. Kyle Little, Compliance Manager
Daniels Sharpsmart, Inc.
111 West Jackson Blvd., Suite 720
Chicago, IL 60604

Subject: New Permit Application, Determination of Completeness and Technical Review
Daniels Sharpsmart, Inc.
Gaston County, DIN 26581

Dear Mr. Little:

On July 26, 2016 the Division of Waste Management, Solid Waste Section (Section) received a new permit application from Daniels Sharpsmart, Inc. (Company) entitled;

Regulated Medical Waste Processing & Treatment Permit Application for; Daniels Sharpsmart, Inc., 1851 Chespark Dr., Gastonia, NC 28052. Prepared by Daniels Sharpsmart, Inc. July 2016. DIN 26531.

Determination of Completeness

The Section has performed a review of the Company's application for a determination of completeness and determined the application is complete, in accordance North Carolina General Statute NCGS 130A-295.8(e). A determination of completeness means the application contains the required components in accordance with North Carolina Administrative Code 15A NCAC 13B .1200.

Technical Review

The Section has reviewed the new permit application and requests that the Company address the following items in the application;

1. *North Carolina Department of Environmental and Natural Resources (NCDENR). Page 13.*
Change the name of the department to, North Carolina Department of Environmental Quality (NCDEQ). Also, the facility's inspector is now, Kim Sue at (704) 235-2163.

2. *Signage. Page 14.*

The Company will be required, upon issuance of the permit, to post a sign near the entrance of the facility indicating; facility name, Solid Waste permit number and 24-hour emergency phone number.

Note:

15A NCAC 13B .1203 GENERAL REQUIREMENTS FOR REGULATED MEDICAL WASTE

(a) Regulated medical waste shall be treated prior to disposal. Acceptable methods of treatment are as follows:

- (1) blood and body fluids in individual containers in volumes greater than 20 ml - Incineration or sanitary sewage systems, provided the sewage treatment authority is notified;
- (2) microbiological waste - Incineration, steam sterilization, microwave treatment, or chemical treatment;
- (3) pathological wastes - Incineration.

Waste Acceptance Protocol. Page 17-19.

General – This section of the Operations Plan is confusing to the Section.

3. *Regulated Medical Waste including sharps, Trace Chemotherapy, Non-Hazardous Pharmaceutical, and non-gross anatomical waste will be treated on-site via autoclave (steam sterilization).*
What is the meaning of *non-gross anatomical waste*? How is it different than pathological waste?
4. *Gross anatomical (Pathological) waste will be accepted, processed, transferred, and then treated in accordance with state approved treatment technologies (i.e. incineration).*
What process is proposed? Specify the processing procedures to be followed on-site for this waste type.
5. *Blood and Body Fluids brought to the facility are already properly packaged and treated in accordance with NCDENR regulation.*
See the note above, describe how *Blood and Body Fluids* will be treated before arriving at the facility?
6. *Pathological Waste: Brought to this facility in bagged, tied, closed, puncture-resistant, properly labeled containers, and transferred at our facility for off-site treatment.*
See item number 2 (above) and ensure descriptions do not contradict one another. Indicate in the Operations Plan, where Pathological Waste will be treated and the type treatment it will receive.?
7. *Trace chemotherapy is defined below as vials or other containers that have less than 3% of the original contents by weight, after removing as much of the chemotherapy feasible. It also includes the chemotherapy remaining in all needles, bags, tubing, containers, gloves, and gowns used during chemotherapy infusions. When less than 3% of the original content remains in total, the items may be considered RCRA empty.*
Be aware that the processing of this waste does not fall within 15A NCAC 13B .1200 requirements. Currently EPA has been recommending to processors to incinerate chemo waste as autoclaving may release chemo-toxic waste through the steam. Please provide the appropriate regulation and/or policy that allows autoclave sterilization treatment of the waste type.

Should you have any questions regarding this matter contact me at (828)296-4704 or larry.frost@ncdenr.gov.

Sincerely,

Larry Frost, Engineering Project Manager
Permitting Branch, Solid Waste Section
Division of Waste Management, NCDEQ

ec: Bill Patrakis – SWS/RCO
Kim Sue – SWS/MRO