From:	Barry Fernandez
To:	Carman, Roger
Cc:	Kantor, Karen E.; Winston, Kathy
Subject:	RE: Clean Fuels of Florida - Response to meeting on 02-17-16 and Inspection Report dated 04-14-15 EPA ID#FLD984171256
Date:	Wednesday, March 9, 2016 5:05:17 PM
Attachments:	Clean Fuels Rx Policies & Procedures (DDC).pdf UPW Training Sign In 08-2015.pdf

Mr. Carman,

Thank you for your time on the phone this afternoon. As discussed, I will be out of the office for about ten days. Nonetheless we are working to get you all of the information requested in order to bring this to a conclusion. In the meantime I have attached a copy of our most recent training record and a copy of our Restricted Rx Policies and Procedures.

Though I will be out of the office I will still receive and send emails.

Best Regards,

Barry Fernandez, President
Mobile (305) 216-4941 barry@clean-fuels.net
Office (954) 791-9588 Fax (954) 791-9366
2635 NE 4th Avenue | Pompano Beach, Florida 33064
www.clean-fuels.net

From: Carman, Roger [mailto:Roger.Carman@dep.state.fl.us]
Sent: Tuesday, March 01, 2016 2:59 PM
To: Barry Fernandez <barry@clean-fuels.net>
Cc: Kantor, Karen E. <Karen.E.Kantor@dep.state.fl.us>; Winston, Kathy <Kathy.Winston@dep.state.fl.us>
Subject: Clean Fuels of Florida - Response to meeting on 02-17-16 and Inspection Report dated 04-14-15 EPA ID#FLD984171256

Mr. Fernandez,
During our meeting with you on 02/17/16, you were requested to provide us copies of the UPW training records and your SOP covering how UPW containers are sorted. We agreed that you would submit this information by February 24, 2016. We have not received the requested information as of this date.

It is the Department's desire that you are able to document compliance or corrective actions

concerning the potential violations identified in the inspection report dated 04/14/15. Therefore, we expect a full written response to any outstanding violations, listed in the final inspection report dated 04/14/15, that are not addressed by the above documents. This is not an extension of your response deadline noted above, and your failure to respond promptly in writing (or by e-mail) may result in the initiation of formal enforcement proceedings.

Sincerely,

Roger Carman
Environmental Specialist III
Compliance Assurance Program
Florida Department of Environmental Protection
3301 Gun Club Road
MSC 7210-1
West Palm Beach, FL 33406
PH: 561.681.6720
Email: Roger.Carman@dep.state.fl.us

Clean Fuels of Florida, Inc.

Restricted Rx Drug Policies & Procedures

Introduction

The following Policies and Procedures are guidelines to be followed when managing prescription drugs at Clean Fuels of Florida, Inc. They have been developed in accordance with Florida Department of Health – Board of Pharmacy, Drugs, Devices and Cosmetics document entitled "Guidance on Drafting Policies & Procedures".

Receipt

1. **How will you determine that you are purchasing and receiving prescription drugs from a person permitted under The Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes?**

    - Prior to arranging for pickup, or the receipt of waste pharmaceuticals at the facility, all customers are required to have an EPA ID Number as outlined in 62-730.186 F.A.C. and/or be permitted by the Department of Health pursuant to Chapter 499 F.S. or 64F-12.023 F.A.C.
    - This information to be independently verified by Clean Fuels personnel by obtaining copies from the customer, contacting the appropriate Agencies and/or searching their on-line database if available.
    - No prescription drugs are to be accepted from customers not meeting the above criteria.

2. **Who will accept prescription drug products into your facility?**

    - All pharmaceutical waste will be received at the Facility by the Operations Manager, or his designated personnel.

    How will your company assure that it is not accepting a product that is contaminated or otherwise unfit for further distribution and that the drug is properly labeled?

    - <u>All</u> pharmaceuticals received at the Facility is considered Waste as defined by 62-730 F.A.C. and is therefore assumed to be contaminated, adulterated, expired, partially used, and/or otherwise unfit for use, resale, credit, donation or consumption by humans or animals and is to be managed as hazardous waste in accordance with EPA, DEP and DOH.

3. **What records (and elements on the records) will you require to document the receipt of prescription drugs by your company and how will you keep track of these records?**

    - All pickup of waste pharmaceuticals will be documented on a hazardous waste manifest or other shipping document in accordance with applicable EPA, DEP and DOT regulations.
    - Inbound shipments are received at the Facility and counted.
    - All records will be kept for no less than 3 years.
    - These records are to be kept at the Facility under the care and custody of the Operations Manager or his designated personnel.

4. **If pedigree papers are required by law and received, how will you assure that the correct pedigree papers accompany the prescription drugs when the drugs leave your facility?**

    - Not Applicable

Storage

1. **How will you maintain your facility in a clean and orderly manner?**

    - Inspections are to be carried out twice per week.
    - A log of said inspections is maintained onsite.

2. **How will you assure that prescription drugs are stored in a manner free from infestation?**

    - All waste pharmaceuticals are to be stored in non-leaking, UN-Rated containers.
    - Containers are kept closed at all times unless adding or removing waste pharmaceuticals in accordance with 62-730.186 F.A.C.
    - All areas of the Facility are to be kept clean and orderly at all times.
    - Any sign of rodents, insects or pests shall be immediately mitigated by contacting a qualified pest control contractor.

3. **What have you done to assure that all prescription drugs are adequately secured at all times?**

    - During normal business hours, the facility is available only to company employees and is physically monitored at all times.
    - Only authorized personnel are allowed in the container storage area unless escorted by a duly authorized employee.
    - After business hours, the premises are remotely monitored electronically by our security company.
    - Security and surveillance systems are installed at the facility.

4. **What have you done to assure that access to prescription drugs is restricted to authorized persons?**

    - With the exception of the main office lobby, all perimeter doors and interior access doors are kept locked unless being used.
    - Signs and barriers are in place indicating that access is restricted to authorized personnel only.
    - Fences, barbed wire, reinforced doors, exterior lighting, alarm system and monitoring, are in place to secure the Facility during and after hours.
    - Emergency contacts are on file with the alarm monitoring company should an alarm engage after business hours.
    - Company policy is to have police dispatched any time there is an alarm.

5. **How will you determine what temperature requirement applies to each prescription drug received in your facility and how will you assure that these drugs are stored under appropriate temperature and humidity conditions?**

    - Clean Fuels is not required to meet temperature storage requirements pursuant to 64F-12.023(4)(a).

6. **How and when will you monitor temperature and humidity conditions?**

    - Not Applicable

Inventory

1. **When and how often will you conduct a physical inventory count? How will you maintain an accurate inventory count?**

    - Physical inventory will be conducted at time of pickup and as waste segregation activities are being done.
    - Hard copies of all container receipts are kept on file.

2. **By what means will you ensure that the drugs received first will be distributed first?**

    - Waste pharmaceuticals will not be distributed, but rather destroyed.
    - Hazardous and non-hazardous waste pharmaceuticals will be shipped out of state for destruction no less than every six months pursuant to our Universal Pharmaceutical Waste registration with the Florida Department of Environmental Protection 62-730.186 F.A.C.
    - The receiving facility will be a federally permitted RCRA hazardous waste incinerator, audited by Clean Fuels and pre-approved as a qualified vendor.

3. **How and where will the quarantine section be identified? What is to be placed in the quarantine section?**

    - All pharmaceuticals will be considered quarantined upon receipt by Clean Fuels.

Distribution / Disposition

1. **Under what conditions will distribution / disposition records be prepared (sales, returns, destruction, etc.)?**

    - A Manifest will be generated upon shipment of waste pharmaceuticals to a destruction facility in accordance with USEPA, DOT and FDEP regulations.
    - Upon receipt by the destination facility, a certified copy of the Manifest is returned to Clean Fuels indicating receipt, pursuant to Federal law.
    - A Certificate of Destruction is also sent to Clean Fuels once the waste has been treated.
    - These documents are maintained for a period of not less than three (3) years.

2. **What elements will you include in the distribution / disposition records of prescription drugs?**

- All in-bound and out-bound Universal Pharmaceutical Waste will be transported/distributed using a Hazardous Waste Manifest.

- The HW Manifest is required to contain the following information:
  - Generating Facility Information (shipper)
  - Emergency contact information
  - Transporter(s) information
  - Designated facility information
  - Waste description, waste codes, type, volume and quantity of containers and weight
  - Date shipped
  - Date received by destination facility
  - Applicable treatment codes

3. Is additional information / records required to support the distribution (prescription or other order, export documentation, etc.)?

- US Environmental Protection Agency Hazardous Waste Manifests System
- Accompanying container inventory (depending on waste type, shipment type, facility requirements, etc.)
- Certificate(s) of Destruction

4. How will you obtain all required information; where will it come from?

- Pharmaceutical information will come from one or multiple sources including (but not limited to):
  - Shipper's inventory
  - Customer formulary
  - Clean Fuels physical inventory
  - National Drug Code (NDC) data sources
  - MSDS or other manufacturers documentation
  - Consumer packaging and/or labeling
  - Any other resources that may become available

- Manifesting information will be obtained from:
  - Generator, transporter(s) and destination facility registrations, licenses and permits
  - EPA listed and characteristic waste codes (40 CFR 261)
  - DOT Hazard Class listings and descriptions (49 CFR 172)

5. How will you determine whether the purchaser and the recipient are authorized to purchase or receive prescription drugs?

- Clean Fuels conducts environmental audits and site visits of destruction facilities and maintains records on file of each destination facility and copies of permits, licenses and registrations.

6. **How will you determine whether pedigree papers are required for the distribution of prescription drugs? If required, how will you provide pedigree papers for the distribution of prescription drugs?**

    - Not Applicable

Record Maintenance / Retrieval / Retention

1. **What records are required to be prepared and/or maintained?**

    - Hazardous Waste Manifests (in-bound and out-bound), certificates of destruction, container inventory, container inspection logs, all personnel training records, are all required to be kept for three (3) years.

2. **Which records will be prepared and maintained by hand and which through automation?**

    - Any records prepared electronically are stored on company server which automatically backs up every evening.
    - In addition, hard copies are maintained of all records.

3. **If you use a computerized record keeping system, what controls or preventative measures have you put in place to prevent/deter theft or tampering with these records? How will you avoid the unintentional loss of data; i.e., what type of back-up procedures do you have for automated records?**

    - Hard copies are maintained of all records.
    - Any records prepared electronically are stored on company server which automatically backs up to a second, external server, every evening.
    - Servers are password protected and available to senior management only.

4. **How will you assure that you maintain records for at least two years after the disposition of the prescription drugs?**

    - Records are maintained for three years pursuant to 62-730.186 F.A.C.
    - Archives are kept securely by senior management.

5. **How will records be readily available and immediately retrievable for inspection at the permitted establishment?**

- Hard copies of records are kept by the Operations Manager and are available for inspection at all times.

6. **If you share a facility with another person or business or engage in other business activities, how will you segregate records for activities under the Chapter 499 permit?**

    - Clean Fuels does not share a facility with anyone.

Natural Disasters / Declared Emergencies

How will you prepare for, protect against and handle a crisis brought on by a strike, fire, flood, or other natural disaster and declared emergencies. Address security, continued operation of the facility - back-up provisions for ongoing services to customers, assessment of damage to prescription drugs and appropriate disposition of damaged product.

- Our Disaster Preparedness Policy and Contingency Plan contain provisions for the preparation, response and assessment of emergencies and disasters, natural or otherwise.

Training Record

Facility Name: Clean Fuels of Florida, Inc.

Department: In-House Ops, Admin, Transportation

Training Subject: RCRA / DOT HMR, HMT / UPW / Haz Wopcer

Date/Time: August 26, 2015

Attendance Sign In

Attendee Name	Title or Position	Signature	Hire Date
JACK GILLIES	GENERAL MANAGER		2/8/13
PAULETTE FERNANDEZ	OFFICE MANAGER	Paulette Fernandez	6/15/13
DJ Fenstermaker	warehouse/Driver		5/12/14
Matt Noland	Warehouse manager		8/5/13

Instructor: Barry Fernandez Signature: