

**HAZARDOUS WASTE SECTION - COMPLIANCE BRANCH
FILE TRANSMITTAL & DATA ENTRY FORM**

Facility ID Number: NCR000005173

Facility Name: Banner Pharmacaps, Inc.

Document Group: Inspection/Investigation (I)

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Author(s) of Document: Jenny Patterson

Inspector Name: Jenny Patterson

Suborganization: Eastern Region

County (if not on report): Guilford

**STATE OF NORTH CAROLINA
DEPARTMENT OF ENVIRONMENTAL QUALITY
DIVISION OF WASTE MANAGEMENT
HAZARDOUS WASTE SECTION**

COMPLIANCE EVALUATION INSPECTION (CEI) REPORT

1. FACILITY INFORMATION:

Facility Name: Banner Pharmacaps, Inc.
EPA ID Number: NCR 000 005 173
Type of Facility: Large Quantity Generator
Facility Location: 4125 Premier Drive, High Point, NC 27265-8144
Mailing Address: Same as facility location address
County: Guilford

2. FACILITY CONTACT: Sam Chewning – Safety, Health and Environmental Manager,
Banner Pharmacaps
Email: Samuel.chewning@patheon.com
Phone: 336-812-8700 ext. 3225

3. INSPECTION PARTICIPANTS: Sam Chewning (Banner Pharmacaps) and Jenny Patterson (NCDEQ)

4. DATE OF INSPECTION: January 21, 2016

5. DATE OF LAST INSPECTION: The facility was last inspected (CEI) on May 1, 2013 with no violations cited.

6. PURPOSE OF INSPECTION: Audit to determine compliance with regulations described at 40 CFR 261, 262, 265, 266, 268, 273 and 279; Title 15A of the North Carolina Administrative Code (NCAC) Chapter 13; and the North Carolina General Statutes (NCGS).

7. FACILITY DESCRIPTION:

Banner Pharmacaps, Inc. (Banner Pharmacaps) develops and manufactures pharmaceutical gelatin-based drug delivery capsules -- both softlets and softgels. In addition, Banner operates as a specialty research and development pharmaceutical company. Banner Pharmacaps began operation at this location in 1996. The facility was built new in 1995. Banner Pharmacaps, Inc. was acquired by Patheon, Inc. on December 14, 2012. Patheon, Inc. is a global provider of contract development and manufacturing services to the global pharmaceutical industry.

The Banner Pharmacaps campus consists of two buildings. One 40,000 square foot building consists mainly of offices. Hazardous waste is not generated in this building. The other building is 234,000 square feet and houses the manufacturing operation, warehouse space, offices and eight analytical and QA/QC laboratories

Banner Pharmacaps first notified with the Hazardous Waste Section as a small quantity generator (SQG) on August 16, 2000. The facility renotified as a large quantity generator (LQG) of hazardous waste in April 14, 2003, and has operated as a LQG ever since.

General Information:

- Legal owner of business: Patheon, Inc., 4815 Emperor Blvd., Suite 300, Durham, NC 27703-8470
- Legal owner of property: From Guilford County GIS - Banner Pharmacaps, Inc., 4125 Premier Drive, High Point, NC 27265
- Acreage: 51.31 acres
- Operating shifts: Facility operates 24 hours a day, 7 days per week. There are five shifts – four manufacturing and one daily 9 am to 5 pm shift.
- Number of employees: 480
- Water supply (municipal or well): Municipal (City of High Point)
- Municipal sewer/septic/on-site treatment facility: Municipal (City of High Point)
- Number of on-site water wells: None
- Distance to closest off-site well: Unknown
- Closest private residence: Approximately .25 miles from facility

8. WASTE STREAMS INCLUDE:

Hazardous waste is primarily generated from the on-site laboratories:

- D001/F003/F005 – Waste flammable liquids (acetonitrile, methanol)
- D001 – Waste flammable liquids (isopropyl alcohol, naphtha)
- D002 – Waste corrosive liquid (organic hydrochloric acid, acetic acid)
- D001 – Waste flammable liquids (methanol, ethanol)
- D001/D002/F003 – Waste flammable liquids (methanol, sodium hydroxide)
- D001/D019/D022/F002/F003 (hexane, methylene chloride)
- U165 – Waste naphthalene crude
- D005/D008/P075/P087/P105/U068 – Waste toxic liquids (Lab pack chemicals)
- D001/D003/U123 – Waste corrosive liquids, flammable (Lab pack chemicals)
- D002/D008 – Corrosive liquids (Lab pack chemicals)

Waste oil: The facility generates waste vegetable oil which will be used by another facility for biodiesel production. The facility also generates a waste hydraulic fluid and has made the determination that after use, the hydraulic fluid is non-hazardous.

Universal lamps and batteries are also generated and handled at the site.

9. AREAS OF REVIEW AND EVALUATION:

- **Emergency Preparedness and Prevention:** The facility is operated and maintained to minimize the possibility of fire or any unplanned sudden or non-sudden release of hazardous waste that could threaten health or the environment. The facility has an internal alarm that provides emergency instruction to personnel in the event of an emergency and facility personnel who handle hazardous waste in the storage area have access to two way radios as well as have access to cell phones to summon emergency assistance if necessary. The facility has fire extinguishers and spill control equipment available near the hazardous waste storage areas. The emergency equipment is tested and maintained. Fire extinguishers are inspected monthly by facility personnel. The alarm system is tested monthly and during evacuation drills. The sprinkler system is inspected monthly with the hydrants and photoionization detectors checked weekly and flushed weekly. The facility maintains twenty-four inches of aisle space in the hazardous waste storage areas. Arrangements have been made with the local emergency authorities to familiarize them with the facility and the hazardous waste handled at the facility. Guilford County Emergency Services acknowledged receipt of the arrangement letter and contingency plan in a letter to Banner Pharmacaps in April 2008.

- **Contingency Plan:** The facility has a document called an Integrated Spill Contingency Plan/Emergency Action Plan and maintains this plan on site. The plan was last updated on October 30, 2012. The contingency plan describes the actions personnel must take to respond to an emergency (fire, explosion or spill), a list of emergency coordinators (Sam Chewning – Primary Emergency Coordinator) with the home and work address and phone number; a description of the arrangements made with the local emergency authorities; a physical description of the emergency equipment used at the less than 90 day storage area in the event of an emergency with the location of the equipment and a brief description of the capabilities of the equipment; a description of the evacuation routes from the less than 90 day storage area and a description of the signal used to begin evacuation of the facility. Copies of the contingency plan were submitted via E-Plan and by mail to the local emergency authorities.
- **Waste Minimization Plan or On-site Efforts:** Waste minimization efforts at the facility are implemented in the form of good housekeeping and off-site recycling, but technical limitations of the production process and regulatory burdens inhibit further recycling.
- **Training Records:** RCRA training was last performed on March 24, 2015. The facility maintains job titles and a job description for personnel with hazardous waste management duties. The job title of “Hazardous Waste Management Associates” has been assigned to personnel with hazardous waste management duties and includes the following personnel: Sam Chewning, Seth Hart, David Crowley, Todd Zorn and Corey Jinnette. All of these people receive annual training which includes a review of the handling, transfer, storage and disposal of hazardous waste; PPE requirements; Hazard Communication, Emergency Action Plan; Spill Plan; RCRA requirements and DOT requirements. The facility utilizes contractors from Southern Logistics and Environmental, LLC for some of the hazardous waste management duties. Contractors attend site specific training which includes a review of the contingency plan and the facility maintains job titles/descriptions and documentation of training for the contractors performing hazardous waste management duties.

On the day of the inspection, RCRA training was reviewed for Corey Jinnette and Seth Hart who sign hazardous waste manifests. They both received RCRA training March 24, 2015.

If facility personnel with hazardous waste management duties teach the RCRA training, documentation of their training must be maintained. Conducting the training alone is not adequate to fulfill the documentation requirements of RCRA training.

- **Inspection Records:** The facility performs weekly inspections of the hazardous waste storage areas and documents them as required. The facility maintains three years of weekly inspections on site. Weekly inspections from January 1, 2015 through December 31, 2015 were reviewed. As part of the weekly inspection, the facility also checks container labels, that containers are closed, adequate aisle space is available, that containers are in good condition, waste is not on site for more than 90 days, and that adequate/appropriate PPE and emergency equipment is available.
- **Manifests/Land Disposal Restrictions:** Manifests and land disposal restrictions for the time period of 2014 through January 14, 2016 were reviewed and found to be complete. The facility maintains at least three years’ worth of manifests on site. The facility uses the following hazardous waste transporters and hazardous waste treatment, storage and disposal (TSD) companies:

Transporters:	Southern Logistics & Env.	NCR000163832
	Republic Env. Sys (Trans Group)	PAD982661381
TSD:	DART Acquisitions	NCD121700777

- **Biennial Report:** The 2013 Biennial Report was submitted by facility on February 26, 2014. The facility maintains a copy of the biennial report on site. The 2015 Biennial Report will be due on March 1, 2016.
- **Satellite Accumulation Areas:** The following satellite accumulation areas were reviewed during the inspection:
 - **Quality Control Instrument Lab:** There are several banks of High Performance Liquid Chromatography (HPLC) equipment in this lab. The waste from the HPLCs is piped to a 30-gallon container located at the end of the lab bench. At the end of one lab bench there is a spill pallet with two 30-gallon containers. One 30-gallon container is used for the accumulation of the HPLC waste and one 30-gallon container is used for mixed solvent waste from standards. One 5-gallon container is used for the accumulation of waste HPCL vials. All satellite accumulation containers were observed in compliance.
 - **Quality Control Chemistry Lab:** There are three 30-gallon plastic containers used for the accumulation of waste acids, waste bases (caustic) and waste flammable liquids. All of these containers were observed labeled properly. Plastic funnels are used in the waste acid and waste caustic drums and the facility has fabricated a special “push pin” that is affixed to the funnel to ensure the funnel is securely closed. This closure device is corroding needs to be replaced. All of the 30-gallon hazardous waste containers are placed in secondary containment and have ventilation ducts near the containers. Several 2.5-gallon flame arrester containers are also used for the accumulation of chlorinated waste. All satellite accumulation containers were observed in compliance.
 - **R&D Lab (Analytical):** This lab has one 30-gallon metal container used for the accumulation of mixed solvents and several 2.5-gallon flame arrester containers, located throughout the laboratory and at the HPLC equipment, and used for the accumulation of HPLC waste and chlorinated solvent waste. Two 1-gallon containers are used for the accumulation of HPLC vials. All satellite accumulation containers were observed in compliance.
 - **R&D (Materials):** This lab has one 2.5-gallon flame arrester can used for the accumulation of waste from analytical equipment and chlorinated solvents. There is also one 5-gallon container used for the accumulation of waste vials. All satellite accumulation containers were observed in compliance.
 - **Technology Lab:** This lab has three 2.5-gallon containers used for the accumulation of waste solvent generated from the HPLC equipment. All satellite accumulation containers were observed in compliance.
 - **Pharmaceutical Development Services (PDS) Lab:** This lab has one 30-gallon container used for the accumulation of mixed solvents, one 5-gallon container used for the accumulation of waste HPCL vials, and one 2.5-gallon container used for the accumulation of waste generated from HPLC equipment. All satellite accumulation containers were observed in compliance.
 - **Lab Pack Cage:**
This satellite area is located inside the building on the QC loading dock and consists of a locked cage for out of date chemicals. The cage is not at or near the point of generation so it is locked to ensure it is maintained under the control of the operator. The facility has developed an SOP for the placement of materials in this area. Chemists place materials on the top shelf of a locked flame cabinet that they can no longer use in their respective laboratories. On a weekly basis, Mr. Chewning, and other trained personnel, performs a waste determination on

these materials. If the material is determined to be non-hazardous or can be used in a different laboratory, the material is removed from the cabinet and managed accordingly. If the determination indicates the material is a hazardous waste, then it is labeled with the words "Hazardous Waste" and moved to the lab pack cage which is next to the flame cabinet. Inspections are performed on the flame cabinet to ensure that the SOP is maintained. On the day of the inspection, the containers were observed in compliance.

- **Storage Areas:**

- **Outside Hazardous Waste Storage Area:** This storage area consists of one locking metal shed with internal secondary containment. This less than 90-day storage area is located outside, behind the facility. On the day of the inspection, there was one 55-gallon container of mixed solvents, two 30-gallon containers of mixed waste, one 55-gallon container of HPLC vials and one lab pack of P-listed waste. All of these containers were labeled, observed closed and marked with an accumulation start date. Twenty-four inches of aisle space was maintained in the hazardous waste storage area.
- **Universal Waste Storage Areas:** The facility generates universal waste lamps and batteries and stores them in the warehouse near the maintenance area. On the day of the inspection, the boxes containing used lamps and the plastic containers containing used batteries were observed closed and labeled properly. The facility maintains manifests shipping documents to show universal waste does not remain on site for more than one year.

10. VIOLATIONS: There were no violations noted during the Compliance Evaluation Inspection conducted on January 21, 2016.

11. ACTION ITEMS:

- The closure devices used on the plastic funnel in the Quality Control Chemistry Laboratory is corroding and needs to be replaced.
- If facility personnel with hazardous waste management duties teach the RCRA training, documentation of their training must be maintained. Conducting/presenting the training alone is not adequate to fulfill the documentation requirements of RCRA training.



Date: February 12, 2016

Jenny Patterson, Environmental Senior Specialist

North Carolina Department of Environmental Quality
Division of Waste Management
Hazardous Waste Section

Jenny.Patterson@ncdenr.gov
Phone: 336-767-0031