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DIVISION OF WASTE MANAGEMENT
HAZARDOUS WASTE SECTION

Your Name: Jenne Walker

Document Category: Facility

Document Group: Inspection/Investigation (I)

Document Type: Compliance Evaluation Inspection (CEI)

EPA ID: NCD101740215

Facility Name/Subject: GlaxoSmithKline

Document Date: 01/25/2017

Description: no violations cited, EPA led inspection

Author: Jenne Walker

Branch/Unit: Compliance Branch-Eastern Region

Facility/Site Address: 1011 Arendell Ave

Facility/Site City: Zebulon

Facility/Site State: North Carolina

Facility/Site Zipcode: 27597

Facility/Site County: Wake

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

RCRA COMPLIANCE EVALUATION INSPECTION (CEI) REPORT

1. FACILITY INFORMATION

Facility Name: GlaxoSmithKline (Zebulon)
EPA ID Number: NCD 101 740 215
Type of Facility: Large Quantity Generator (LQG)
Facility Location: 1011 Arendell Avenue, Zebulon, NC 27597
Mailing Address: PO Box 1217, Zebulon, NC 27597
County: Wake

2. FACILITY CONTACT:

David Schaefer, EHS Engineer - GlaxoSmithKline
office telephone: (919) 269-1966; david.x.schaefer@gsk.com

3. EVALUATION PARTICIPANTS:

David Schaefer – GlaxoSmithKline
Melanie Szydlik-Hawkes – GlaxoSmithKline
Jenne Walker - Hazardous Waste Section, Division of Waste Management, NC DEQ
Don Burke - Hazardous Waste Section, Division of Waste Management, NC DEQ
William Kappler – Environmental Protection Agency, Region 4

4. DATE OF INSPECTION: January 25, 2017

5. PURPOSE OF SITE VISIT:

An EPA lead inspection was conducted at the subject facility by William Kappler - US EPA Region 4 and North Carolina Department of Environmental Quality inspectors Jenne Walker and Don Burke to evaluate the facility's compliance with the hazardous waste management regulations (also known as the Resource Conservation & Recovery Act, or RCRA regulations). The hazardous waste management regulations can be found at Title 40 of the Code of Federal Regulations (40 CFR), Parts 260-270, 273 and 279 and at Title 15A Chapter 13A of the North Carolina Administrative Code (NCAC).

6. FACILITY DESCRIPTION:

The GlaxoSmithKline (Glaxo) facility in Zebulon formulates, mixes and packages a variety of pharmaceutical products including solid dose and inhaler dispensed products. The Metered Dose Powdered Inhaler (MDPI) Facility manufactures the 'Advair discus' medication. The facility was last inspected on February 26, 2013 with no violations cited. GlaxoSmithKline is listed as a Large Quantity Generator (LQG) of hazardous waste.

General Information

1. Legal owner of business & property: GlaxoSmithKline
2. Square Footage: ~ 700,000 sq. ft.
3. Acreage: ~293 acres
4. Number of employees: ~ 785
5. Operating hours: 24 hours/day
6. Sanitary Sewer and Water supply are provided by the City of Raleigh.
7. Distance to closest off-site well: ~1/5 mile
8. Distance to closest private residence: < 1/2 mile

7. WASTE STREAMS

Glaxo's largest hazardous waste streams include a significant quantity of waste flammable liquids (mixed solvents), corrosive liquids and a variety of labpack chemicals. Routinely generated waste streams include:

D001, F003 – waste flammable liquids (methanol, acetonitrile)

D001 – waste flammable solids, organic (IPA contaminated wipes)

D001 – waste flammable liquids (vials)

D001 – waste aerosols (paint, degreasers from maintenance ops.)

D001 – waste isopropanol

D001, D002, D010 – waste oxidizing liquids, corrosive (hydrochloric acid, chromium)

D002 – waste corrosive liquids, toxic (lab chemicals)

D002 – waste corrosive liquids, basic (lab chemicals)

D002 – waste sulfuric acid

D002 – waste corrosive liquids, acidic, inorganic (hydrochloric acid, phosphoric acid)

Other Types of Waste:

Universal Waste – used batteries and used lamps containing mercury

Used Oil

8. AREAS OF REVIEW & FINDINGS:

PHYSICAL INSPECTION/FACILITY WALK THROUGH

Quality Control Laboratory

Quality Control testing of MDPI and solid dose manufactured products is conducted in this laboratory. Hazardous waste is accumulated in containers at approximately ten satellite accumulation areas throughout the lab.

Manual Dissolution Area – One 5-gallon container was accumulating waste methanol and acetonitrile; one 30-gallon container was accumulating waste corrosive liquid and one 14-gallon container was accumulating spent solvent contaminated wipes. Each container was closed and marked with the words 'hazardous waste'.

Former PACE/MDPI Team Area – One 14-gallon container was accumulating spent solvent contaminated wipes. The container was closed and marked with the words 'hazardous waste'.

MDPI Excellence Area – One 5-gallon container was accumulating waste methylene chloride and acetone; two 2-gallon containers were accumulating waste methanol and acetonitrile. Each container was closed and marked with the words ‘hazardous waste’.

MDPI Room (POC Unit) – One 5-gallon container was accumulating waste methanol and chloroform. The container was closed and marked with the words ‘hazardous waste’.

Particulate Matter Room – One 5-gallon container was accumulating waste methanol and chloroform. The container was closed and marked with the words ‘hazardous waste’.

Cascade Impaction Area – Six ASRS instruments were observed in this room. Waste methanol and water are generated from the instruments. This hazardous waste stream is collected and accumulated through the facility’s solvent collection system. Each ASRS instrument is connected to a stainless-steel pipe. The piping is constructed with welded connections and is gravity fed under the flooring of the lab to a 15-gallon tank located in Building 134 (the solvent collection system).

Solid Dose Testing Weight Room – One 14-gallon container was accumulating spent solvent contaminated wipes. The container was closed and marked with the words ‘hazardous waste’.

Oral Solid Dose Testing – One 5-gallon container accumulating waste methanol and acetonitrile, two 5-gallon containers accumulating corrosive liquid and one 5-gallon container accumulating spent solvent contaminated wipes were observed. Each container was closed and marked with the words ‘hazardous waste’.

Discard Sample Area – Three 5-gallon containers were observed accumulating hazardous waste. Each container was closed and marked with the words ‘hazardous waste’.

Quality Control Laboratory Bench Areas

Approximately 50 HPLC instruments are used in this laboratory. The HPLC instruments are connected to stainless steel pipe which discharges the hazardous waste by gravity to the solvent waste collection system. The facility tags the ancillary equipment with numbered white labels for organic air emission monitoring. HPLC waste may in some circumstances be accumulated in containers.

Laboratory Bench 7

Inspectors observed several HPLCs located on this bench. Two 5-gallon containers were accumulating waste methanol and one 2-gallon container was accumulating waste HPLC vials. Each container was closed and marked with the words ‘hazardous waste’.

Laboratory Bench 9

Several HPLCs were observed on this bench. Hazardous waste is discharged to the solvent waste collection system.

Laboratory Bench 11

Several HPLCs were observed on this bench. Hazardous waste is discharged to the solvent waste collection system.

Laboratory Benches 13, 20, 24, and 26

Several HPLCs were observed on this bench. Hazardous waste is discharged to the solvent waste collection system.

Tablet Processing Waste Station Bench

Hazardous waste generated from the two tablet processing waste stations is discharged to the solvent waste collection system.

Automated Dose Delivery Room

Two automated dose delivery units are in this room. Each unit accumulates waste methanol and water in a 30-gallon container prior to discharging to the solvent waste collection system. Each container was closed and marked with the words 'hazardous waste'. Inspectors observed the ancillary equipment was tagged with numbered white labels for organic air emission monitoring.

Building 134

Solvent Waste Collection System

The solvent waste collection system consists of a 15-gallon stainless steel tank (15"x15"x15") that is located inside an approximately six-foot deep concrete sump (confined space). The sump is lined with stainless steel and is covered with removable metal grates. Three 55-gallon containers were staged on the metal grates to accumulate hazardous waste pumped in series from the tank through flexible metal lines. The containers were closed and marked with the words 'hazardous waste'. It takes approximately one week to fill one 55-gallon container.

A container storage area is in the same room but adjacent to the wall. One 55-gallon container was observed to be marked with the words 'hazardous waste' and an accumulation start date of 1/25/2017.

As the system is set up, the tank was not accessible for inspection. Glaxo staff moved the three waste containers and the metal grates so that a visual inspection could be performed. The top of the tank was observed to be labeled 'hazardous waste', but the markings were not clearly visible. No evidence of spills was observed.

Inspectors noted a stainless-steel vent pipe from the top of the tank to the rooftop. Glaxo staff stated that a flame arrestor is connected to the top of the vent pipe. One February 3, 2017, Glaxo staff emailed a record of the microFID reading at 0.00ppm obtained from the flame arrestor while the system was operating. The facility also conducted a check of all ports and connections. This resulted in one leak being detected, triggering a 15-day repair.

Main 90-Day or Less Hazardous Waste Storage Area

Main Hazardous Waste Storage - This area is located on the southeastern side of the gated property. Veolia staff transfer containers of hazardous waste from Satellite Accumulation Areas to the main storage area. Each shed is locked, equipped with a spill kit, fire extinguisher, secondary containment and fire suppression system. Signage and contact information is posted in the area.

Hazardous waste was not observed to be stored in shed numbers 1, 2, 3, 5 and 6.

Shed 4 contained two 5-gallon containers and one 15-gallon container of hazardous waste. Each container was closed, in good condition, marked with the words 'hazardous waste' and an accumulation start date of less than 90 days and adequate aisle space was maintained.

A flammable cabinet was observed accumulating several containers of hazardous waste (less than 1 gallon). Some of the containers were possibly accumulating hazardous waste but the markings were unclear. The facility staff immediately corrected the issue.

Quest Building

Universal Waste Storage Area

Universal waste lamps and batteries are routinely stored in this building. Three closed containers were observed to be marked with the words 'universal waste batteries' and an accumulation start date of less than one year.

MDPI 90-Day or Less Hazardous Waste Storage Area

A metal storage shed with sump is utilized as a hazardous waste storage area. The shed is kept locked, contains a spill kit, fire extinguisher and eye wash/shower. Signage and emergency contact information was posted. Inspectors observed ten 55-gallon containers, four 30-gallon containers and one 15-gallon container of hazardous waste. Each container appeared to be in good condition, was closed, marked with the words 'hazardous waste' and an accumulation start date of less than 90 days and adequate aisle space was maintained.

RECORDS & PAPERWORK REVIEW

Manifests & LDRs – Manifests and LDRs generated since the last inspection were reviewed for 2015 through January 2017 and found to be in good order. The following hazardous waste management vendors were utilized during this time frame:

HW Transporters: Clean Harbors Environmental Services, Inc. – MAD 039 322 250
 Robbie D Wood, Inc. – ALD 067 138 891
 Veolia ES Technical Solutions – NJD 080 631 369

HW TSDs: Clean Harbors Reidsville, LLC – NCD 000 648 451
 Veolia ES Technical Solutions – NCD 986 166 338

Weekly Inspection Logs – Weekly container inspection logs were reviewed for each of the facility's 90-day or less hazardous waste storage areas. Records were available from 2014 through January 2017.

Daily Inspection logs for the hazardous waste tank – Daily tank inspection records (a part of the waste solvent collection system) were reviewed for 2016 and 2017.

RCRA Organic Air Emission Records – Glaxo maintains a leak detection and repair plan for the solvent waste collection system. Monitoring points are identified with a white labeling system. Monthly monitoring inspection logs were reviewed from January 2014 through January 2017 and leak detection reports were reviewed for 2015 and 2016.

Contingency Plan – Glaxo’s LQG Contingency plan was last revised in January 2016. The plan listed home address and home and work telephone numbers for emergency coordinators. The plan described procedures for responding to a fire, explosion and hazardous waste/chemical spill including evacuation routes and procedures, a list of emergency equipment, maps and a description of arrangements made with local authorities.

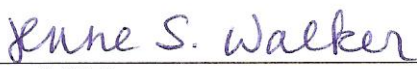
Arrangements with Local Emergency Authorities – Arrangements have been made with the following agencies: Zebulon Police Department, Zebulon Fire Department, Wake County Emergency Management, Wake Medical Center, and the Wake County Sheriff’s Department.

Personnel Training & Job descriptions – RCRA Training records were reviewed for Glaxo’s EHS Staff including David Schaefer, John Byrd, Norman Mitterling, and William Ludlam. Training records were reviewed for Veolia ES Technical Solutions waste management contract employees Gregory Black, Kelly Fox, Larry Cos, Mark Hudson, Norman Anderson, Rashid Edmondson and Randy Wilson.

Biennial Report – A copy of the facility’s last Biennial Report (submitted to NC DWM on 2/4/2016) was on-file and available for review during the inspection. ***The facility’s next Biennial Report is due to NC DWM on or before 3/1/2018*** (for Calendar Year 2017 data).

9. CONCLUSION:

At the time of the inspection, GlaxoSmithKline appeared to be operating in compliance with the hazardous waste management (RCRA) regulations. Please contact Jenne Walker at 919-707-8224 or by email at jenne.walker@ncdenr.gov if you have any questions about this report or maintaining compliance with the NC Hazardous Waste (RCRA) Management Rules.



Jenne S. Walker
Environmental Senior Specialist, NCDEQ

Date signed: April 5, 2017