DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
**ACTIVITY REPORT: Self Initiated Inspection**

FY 2015 Insp

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| **FACILITY:** FERNDALE LABORATORIES INC | | **SRN / ID:** A5290 |
| **LOCATION:** 780 W EIGHT MILE RD, FERNDALE | | **DISTRICT:** Southeast Michigan |
| **CITY:** FERNDALE | | **COUNTY:** OAKLAND |
| **CONTACT:** | | **ACTIVITY DATE:** 10/07/2014 |
| **STAFF:** Iranna Konanahalli | **COMPLIANCE STATUS:** Compliance | **SOURCE CLASS:** MINOR |
| **SUBJECT:** FY 2015 inspection of Ferndale Laboratories, Inc. | | |
| **RESOLVED COMPLAINTS:** | | |

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**Ferndale Laboratories, Inc. (A5290)**
**Parent company: Ferndale Pharma Group, Inc.**
**780 West Eight Mile Road**
**Ferndale, Michigan 48220-2422**

**Subject to existing Area source NESHAP / MACT ZZZZ / MACT 4Z / RICE MACT, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines / Final rule (Page 3568, Federal Register / Vol. 73, No. 13 / Friday, January 18, 2008 / Rules and Regulations / Final rule; Page 51570 Federal Register / Vol. 75, No. 161 / Friday, August 20, 2010 / Rules and Regulations / Final rule;Page 12863 Federal Register /Vol. 76, No. 46 /Wednesday, March 9, 2011 /Rules and Regulations / Direct final rule; amendments for August 20, 2010, final rule; Page 6674 Federal Register / Vol. 78, No. 20 / Wednesday, January 30, 2013 / Rules and Regulations / Final rule. Page 48072 Federal Register / Vol. 79, No. 158 / Friday, August 15, 2014 / Rules and Regulations / Notice of final decision on reconsideration. etc.).** AQD has decided not to take delegation of these standards and therefore no attempt has been made evaluate **Ferndale's** compliance with NESHAP / MACT 4Z. Besides, SI RICE produces only 20 kW of power.

On October 07, 2014, I conducted a level-2 self-initiated inspection of Ferndale Laboratories, Inc. ("Ferndale Labs"), a drug / pharmaceutical manufacturing company, located at 780 West Eight Mile Road, Ferndale, Michigan 48220-2422. The inspection was conducted to determine compliance with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451; Michigan Department of Environmental Quality, Air Quality Division (MDEQ-AQD) administrative rules.

During the inspection, Ms. Cecile Cruz (Phone: 248-548-0900-ext. 522; Fax: 248-548-0470; E-mail: ccruz@ferndalelabs.com), Regulatory Affairs Specialist, Ms. Lori Sloane (Phone: 248-548-0900-ext. 628; Fax: 248-548-0470; E-mail: lslaane@ferndalelabs.com), VP Manufacturing, and Mr. Bill Allen (Phone: 248-548-0900-ext. 628; Fax: 248-548-0470; E-mail: dallen@ferndalelabs.com), Facilities Engineering Supervisor, assisted me.

Ms. Sarah Van Hoof (Phone: 248-548-0900-ext. 467), Manager of Regulatory Affairs, was present. Mr. Richard Hamer (Phone: 248-586-8433; E-mail: rhamer@ferndalelabs.com), VP Regulatory Affairs, did not participate.

Mr. Dave Missovich (Phone: 248-548-0900-ext. 521; E-mail: dmissovich@ferndalelabs.com), Safety Coordinator, separated about February 2014. Mr. Harvey Finzel (Phone: 248-548-

0900-ext. 562; E-mail: hfinzel@ferndalelabs.com), Facilities Director, also separated about February 2014.

Ferndale Labs, with 100,000 sq. ft. FDA-approved facility manufactures drug products and medical devices, such as creams, lotions, ointments, liquid adhesives (devices), etc. It also performs contract manufacturing. Ferndale Labs has 150 (reduced from 170 due to 2014 reorganization) employees.

**Bottle filling and packaging lines (Room 134, HEPA #1)**

One bottle filling line for liquid adhesives devices is present. Two product-filling machines to fill into the tubes --creams, lotions and ointments-- are present. One carton-filling machine to package products is present. One automated tube-filling machine with cartoning system for creams, lotions and ointments is present. All these machines use the building ventilation with HEPA filter (HEPA #1); i.e., there is no dedicated ventilation system. The filters are replaced once in five years. FDA regulated clean room conditions are maintained using HEPA filters.

**Weighing room (Room 118, HEPA #3)**

One weighing room is present. Solids, liquids are weighed and sent to the manufacturing area. The room is equipped with HEPA Filter (HEPA #3) to control dust. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

**Raw materials staging room and mixers (Room 119, 123, 135, 136, HEPA #3 & HEPA #2)**

One raw materials staging room (Room 119) is present. One 150-gallon (Room 136), one 400-gallon (Room 135) and one 40-gallon (Room 134) mixers are present. Mixers are used to make creams, ointments and lotions. 40-gallon mixer is hardly used.

The rooms are equipped with HEPA Filter (HEPA # 2 & 3) to control dust. Rooms 134, 135 and 136 are covered by HEPA #2. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

**Raw materials staging room (Room 111, HEPA #3)**

One raw materials staging room is present. Also, it is equipped with Donaldson Torit HEPA filter (idle on Oct 7, 2014). The filter system is equipped with Magnehelic pressure monitoring device. The filters are replaced once in five years.

The rooms are equipped with HEPA Filter (HEPA #3) to control dust. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

**Tank storage room (HEPA #2)**

One tank storage room is present.

The rooms are equipped with HEPA Filter (HEPA #2) to control dust. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the

room. The filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

**Ultra-pure water**

One RO / CDI system (US Filter Co.) for ultra-pure water is present.

Because topical drugs are manufactured clean room standards are applied to the manufacturing areas. FDA frequently inspects Ferndale Labs.

**Roof-top HEPA filters**

Three banks of HEPA filters are present on the roof-top. These filter systems provide dust control services to all process areas. Each filter system is equipped with a Magnehelic Pressure Monitoring Device. The filters are replaced once in five years. After filtration of dust using HEPA filters, cleaned air is recycled into the plant in heating season (winter). Outside ambient air as fresh make-up air is introduced into the process areas upon cleaning with HEPA filters. Ferndale Labs maintains FDA clean room standard.

**Emergency generator (NG fired SI ICE)**

On roof top one natural gas fired emergency generator (20 kW) is present. This is natural gas fired spark ignition (SI) reciprocating internal combustion engine (RICE). SI RICE was installed about April 2012.

- GENRAC Guardian Series Model No. 0058751 Serial No. 6833287
- Rated capacity: 20 kW
- Non-resettable hours meter is present. Current (10/07/2014) reading: 69.1 hours.
- Maintenance schedule (1/yr.) for oil and filter change is present.

The NG fired SI RICE may be subject to NSPS 4I, 40 CFR, Part 60, Subpart JJJJ—Standards of Performance for Stationary Spark Ignition (SI) Internal Combustion Engines (ICE) for engines of power greater than 19 kW (25 hp) manufactured after January 1, 2009.

Pursuant to 40 CFR, 60.4230(c), Ferndale Labs is not required to obtain Title V / RO Permit.

Ferndale Labs may be able to obtain certificate from the vendor.

*Certified stationary internal combustion engine* means an engine that belongs to an engine family that has a certificate of conformity that complies with the emission standards and requirements in this part, or of 40 CFR part 90, 40 CFR part 1048, or 40 CFR part 1054, as appropriate.

GENRAC Guardian SI RICE is subject to existing Area source NESHAP / MACT ZZZZ / MACT 4Z / RICE MACT, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for

Reciprocating Internal Combustion Engines / Final rule (Page 3568, Federal Register / Vol. 73, No. 13 / Friday, January 18, 2008 / Rules and Regulations / Final rule; Page 51570 Federal Register / Vol. 75, No. 161 / Friday, August 20, 2010 / Rules and Regulations / Final rule;Page 12863 Federal Register /Vol. 76, No. 46 /Wednesday, March 9, 2011 /Rules and Regulations / Direct final rule; amendments for August 20, 2010, final rule; Page 6674 Federal Register / Vol. 78, No. 20 / Wednesday, January 30, 2013 / Rules and Regulations / Final rule. Page 48072 Federal Register / Vol. 79, No. 158 / Friday, August 15, 2014 / Rules and Regulations / Notice of final decision on reconsideration, etc.). AQD has decided not to take delegation of these standards and therefore no attempt has been made evaluate Ferndale's compliance with NESHAP / MACT 4Z. Besides, SI RICE produces only 20 kW of power.

**Boilers**

One Cleaver Brooks CB Package Boiler (Model C-8700-100, 150 psi steam, 4.1 MMBTU per hour, NG only, installed on March 14, 2003) process boiler and one Cleaver Brooks CBH Package Boiler (2 MMBTU per hour, NG only) hot water boiler are present. The boilers are exempt from Rule 336.1201 pursuant to Rule 336.1282(b) and NSPS Dc (< 10 MM BTU / hour).

**Conclusion**

The manufacturing processes are exempt from Rule 336.1201 (Permit-to-Install) pursuant to either Rule 336.1285 or Rule 336.1290.

NAME J Marshall DATE 10/28/2014 SUPERVISOR CTE