DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Scheduled Inspection

N568845005

FACILITY: Perrigo Holland, Inc.		**SRN / ID:** N5688
LOCATION: 13295 REFLECTIONS DR, HOLLAND		**DISTRICT:** Grand Rapids
CITY: HOLLAND		**COUNTY:** OTTAWA
CONTACT: Cris Hillman , Environmental Coordinator		**ACTIVITY DATE:** 06/21/2018
STAFF: Tyler Salamasick	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MINOR
SUBJECT: FY 2018 minor source inspection.		
RESOLVED COMPLAINTS:		

Overview
Perrigo is a manufacturer of over the counter medications. The facility receives raw material and blends them together. The blended medication can be either encapsulated or compressed into a pill. Some of the pills are also coated.

Perrigo is considered to be one stationary source. Perrigo is a minor source of air contaminants and is not subject to the Title V program, which is discussed below, in the regulatory analysis section of this report.

Introduction and purpose
On June 21, 2018 Tyler Salamasick, Environmental Quality Analyst of the Michigan Department of Environmental Quality, Air Quality Division conducted an unannounced, scheduled inspection. of Perrigo. Kevin Walters, Aquatic Biologist of the MDEQ Water Resources Division joined on the inspection for cross training purposes. The MDEQ inspected the facility located at 13295 Reflections Drive, Holland, Michigan. The purpose of the inspection was to determine the facility's compliance with the requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); the Air Pollution Control Rules; and PTI No. 124-11 D.

Facility location
Perrigo is located on the north west end of a small industrial park. The industrial park is located on the north end of Holland, adjacent to a residential area and an agricultural area. The nearest house is approximately 200 feet west of Perrigo's production facility. Perrigo has two sister facilities nearby, one at the south end of Holland and another facility in Allegan.

Facility Changes
Perrigo staff did not identify any major changes at the facility since the last inspection.

Compliance History
The facility has not received any recent complaints or violations. The facility was found to be in compliance with their permit and applicable regulations during the inspection in 2014 and the inspection in 2012.

Observations and facility processes
AQD staff met with Kurt Andree, Support Services Manager, Rod Ruhf, Director of Operations, and Cris Hillman, EHS Engineer II. AQD staff presented their identification and informed the representatives of the intent of the inspection. The facility representative agreed to show the MDEQ the facility and its processes. Cris Hillman was the main point of contact during the inspection and record review.

Perrigo produces generic over the counter medications on multiple production lines. The production lines are assembled per batch and can run for various lengths of time before being disassembled. The facility's processes are described in some detail below. AQD staff observed various stages of the processes, not necessarily in the order listed in the discussion below.

Most of the processes follow a relatively similar flow through the facility, though each product may vary slightly. Perrigo utilizes some combination of material storage, blenders, weigh rooms, multiple blending suites, tablet presses, encapsulation units and pill coating lines. Multiple points of material handling are controlled by various permitted, exempt and internally vented dust pollution control devices.

Material storage and raw material
The storage area primarily consisted of shipping and receiving and a large warehousing area. Most of the materials were received in containers or large totes. The facility did not appear to vacuum products or handle them in a manner that would generate dust during shipping and receive or storage. The storage area was well kept, and I did not observe product spillage.

Weigh rooms
The facility uses multiple weigh rooms to weigh raw materials prior to blending. The weigh rooms utilize a down flow booth to control dust. The weigh rooms are controlled by DC-12. Some of the internal dust control is vented back into the plant, but DC-12 appears to exhaust externally. DC-12 is permitted under PTI 124-11D.

Blending suite
The blending suites use weighed materials, either in drums or totes. The suites are set up per job and have dust control vented through dust collectors. Once blended the medication can be either encapsulated or pressed into a tablet.

Tablet press and encapsulation
Perrigo's tablet process uses a two-story system of hoppers, loading ports and a press. The system loads the medication powder into the press. They press compresses the medication into a pill shape. Any excess dust is collected and controlled. The encapsulation process is similar except instead of pressure the medication is loaded into a capsule which is then sealed with a safety band. Perrigo doesn't encapsulate or press all of the medication at the facility. Some of the materials are blended and packaged into containers as a loose powder instead.

Coating line
Some of the compressed pills are then coated in large rolling machines. The coating process varies greatly from traditional coating. The pills are coated in a large rotary drum that utilizes multiple spray nozzles mounted on a bracket. As the pills tumble they are sprayed with a coating. Any overspray is minimalized in order to maintain product quality. Dust in the system from potential overspray or product breakage is controlled by a dust collector.

Process heat and roof access
While inspecting the facility we also looked at two Clever Brooks boilers. The boilers were both 23 MMBTU per hour. The boilers are also both natural gas fired only. In addition to looking at the boilers we went onto the roof to inspect the emission points. While on the roof I did not observe evidence of opacity from the stacks or fallout of debris. Cris informed me that they conduct routine inspections of the roof and check for any fugitive dust emissions.

Regulatory analysis and compliance evaluation

Facility emission category

Perrigo is a minor source of particulate matter (PM), volatile organic compounds (VOCs), hazardous air pollutants (HAPs), nitrogen oxides (NOx), carbon monoxide (CO) lead (Pb) and sulfur oxides (SOx). The facility's emission units are currently permitted under PTI-124-11D.

Federal Regulations

Perrigo's boilers are subject to 40 CFR Part 60 Subpart Dc Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units.

PTI-124-11D
Emission limits – Perrigo has twenty-two different pound per hour emission rate limits for particulate matter. The emission rate is listed per emission unit in the table below. The emission rates are low, and the expected control efficiency is relatively high. The following emissions are presumed to be met based on equipment design and regular maintenance of the equipment. The emissions are as follows:

Pollutant	Limit	Equipment
1. PM	0.0000165 pph[1]	EUFLUIDBED
2. PM	0.17 pph[1]	EUACP-3
3. PM	0.018 pph[1]	EUACP-4
4. PM	0.018 pph[1]	EUACP-5
5. PM	0.018 pph[1]	EUACP-6
6. PM	0.018 pph[1]	EUACP-7
7. PM	0.018 pph[1]	EUACP-8
8. PM	0.018 pph[1]	EU300MIXERDC#11
9. PM	0.0108 pph[1]	EULINE6DC#15
10. PM	0.0108 pph[1]	EUGRANULATOR
11. PM	0.00000477 pph[1]	EUFLDBDGRANULTR
12. PM	0.56 pph[1]	EUEQ-13
13. PM	0.0265 pph[1]	EUFBG#2
14. PM	0.0108 pph[1]	EUDC#12
15. PM	0.0054 pph[1]	EUDC#23
16. PM	0.0144 pph[1]	EUDC#24
17. PM	0.025 pph[1]	EUFBD#3
18. PM	0.025 pph[1]	EUFBD#4
19. PM	0.0026 pph[1]	EUDC#13
20. PM	0.0032 pph[1]	EUEQ#38
21. PM	0.0072 pph[1]	EUEQ#12
22. PM	0.0037 pph[1]	EUEQ#45

Material limits

The facility has various limits depending on the compound that is used and what control device it is being emitted from. The facility is required to limit the usage in FGPRODUCTION of each raw material that is a toxic air contaminant (TAC) such that the ratio of the amount of each raw material that is a TAC used to the total raw material usage does not exceed the ratio of the allowable concentration to the predicted ambient impact, based on a 12-month rolling time period, as determined at the end of each calendar month, as described by the following equation:

Equation 1: RMR = AC/PAI, where

RMR is the allowed raw material ratio for each raw material (raw material usage divided by total raw material throughput)
AC is the allowable concentration (AQD screening level or value from the table below if there is no AQD screening level for the raw material)
PAI is the predicted ambient impact for total particulate matter, as listed below for each averaging time

1 hour PAI = 54.34 $\mu g/m^3$ 3 hour PAI = 36.48 $\mu g/m^3$
8 hour PAI = 31.11 $\mu g/m^3$ 24 hour PAI = 16.75 $\mu g/m^3$
Annual PAI = 2.61 $\mu g/m^3$

Raw Material	Allowable Concentration ($\mu g/m^3$)	Conc. Averaging Time		Raw Material	Allowable Concentration ($\mu g/m^3$)	Conc. Averaging Time
Acetaminophen	**15**	**Annual**		**Microcrystalline cellulose 102**	**1.0**	**Annual**
Dicalcium phosphate, anhyd gran	**1.0**	**Annual**		**Methocel XD**	**1.0**	**Annual**
Maltodextrin	**1.0**	**Annual**		**Methocel A4M Premium**	**1.0**	**Annual**
Aspirin	**1.0**	**Annual**		**Ascorbic acid**	**1.0**	**Annual**
Orange flavor base	**1.0**	**Annual**		**Oat fiber granulation**	**1.0**	**Annual**
Sugar free orange flavor base	**1.0**	**Annual**		**Calcipure 95A**	**1.0**	**Annual**
Cal Carb 95A	**1.0**	**Annual**		**Vitamin E acetate**	**1.0**	**Annual**
IM Citrucel Prep Granulation 34817	**1.0**	**Annual**		**IM Citrucel Prep Granulation 34818**	**1.0**	**Annual**
Microcrystalline cellulose 101	**1.0**	**Annual**		**Mannitol**	**42.0**	**1 hour**
Naproxen Sodium	**12.0**	**Annual**				

[A] Total raw material throughput shall include all raw materials, including raw materials that are not TACs.

The provided emissions report summarized the data using the above equation to include a maximum RMR along with an Actual RMR and a pass fail notation. No emissions were reported in exceedance of the allowable RMR. AQD staff calculated the percent actual emission vs the allowable emission rate to find which chemicals were being emitted closest to the allowable limit. Guaifenesin was emitted at approximately 32% of its maximum allowable emission rate. The next highest was IM DPDT POLYET GLY 3350 PWD at approximately 26% of its maximum allowable emission rate. The facility appears to comply with the material limits of PTI 124-11D.

Process and operational restrictions
The facility does not have applicable process and operational restrictions specified in the permit.

Design and equipment parameters
The permittee is required to not operate the emission units listed in the permit unless the associated control equipment is installed, maintained, and operated in a satisfactory manner. Proper operation of each of the dust collectors includes submitting an operation and maintenance plan for approval to the District Supervisor within 30 days after permit approval. The facility has submitted operation and maintenance plans to the MDEQ.
Testing and sampling
The facility does not have applicable testing and sampling requirements specified in the permit.
Monitoring and record keeping
The permittee is required to keep records of dust collector inspection data and corrective actions resulting from implementation of the dust collector operation and maintenance plan required by SC IV.1. During the inspection Cris showed me various dust collectors and their pressure drops. Of the equipment observed the processes had appropriate pressure drops. Cris provided me with example reports for equipment maintenance. Cris also provided me with weekly roof inspection reports. The inspection reports are used to monitor and confirm no bags broke and caused fallout of particulate matter on the roof. The permittee appears to be maintaining proper maintenance records.

Reporting
The facility does not have applicable reporting requirements specified in the permit.

Stack restrictions
Perrigo has the following stack restrictions. The exhaust gases from the stacks listed in the table below shall be discharged unobstructed vertically upwards to the ambient air unless otherwise noted:

Stack & Vent ID	Maximum Exhaust Diameter/Dimensions (inches)	Minimum Height Above Ground (feet)
1. SVFLUIDBED[A]	20	36
2. SV4	16	48
3. SV5	16	50.7
4. SV9	18	48
5. SV11[A]	12 x 24	18
6. SVEQ-13	10	48
7. SV14	15	18.5
8. SV15[A]	10 x 16	10

9. SV16	**10**	**40**
10. SV18	**16**	**46**
11. SV20	**15**	**18.5**
12. SV21[A]	**16**	**38**
13. SV22	**12**	**51**
14. SV12	**16**	**51**
15. SV23	**16**	**75**
16. SV24	**24**	**75**
17. SV25	**24**	**75**
18. SV26	**24**	**75**
19. EQ12	**12 x 12**	**48**
20. SV13 [A]	**4**	**16.5**
21. SV38	**6**	**22**
22. SV45	**8**	**75**
[A] These stacks do not exhaust vertically upwards to the ambient air.		

AQD staff did not directly measure the height of the stacks and the building, but I did observe the stack height from the top of the roof. The stacks appeared to be the appropriate size and I did not observe obstructions at the exhaust points of the specified stacks.

Discussion

Compliance statement: It appears that Perrigo is in compliance with the requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); the Air Pollution Control Rules; and 124-11D.

NAME _____ DATE 8/22/18 SUPERVISOR _____