MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY AIR QUALITY DIVISION

January 7, 2015

PERMIT TO INSTALL 124-11D

ISSUED TO
Perrigo Holland, Inc.

LOCATED AT 13295 Reflections Drive Holland, Michigan

IN THE COUNTY OF Ottawa

PENINSULA

STATE REGISTRATION NUMBER N5688

The Air Quality Division has approved this Permit to Install, pursuant to the delegation of authority from the Michigan Department of Environmental Quality. This permit is hereby issued in accordance with and subject to Section 5505(1) of Article II, Chapter I, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended. Pursuant to Air Pollution Control Rule 336.1201(1), this permit constitutes the permittee's authority to install the identified emission unit(s) in accordance with all administrative rules of the Department and the attached conditions. Operation of the emission unit(s) identified in this Permit to Install is allowed pursuant to Rule 336.1201(6).

DATE OF RECEIPT OF ALL INFORMATION REQUIRED BY RULE 203: November 19, 2014		
DATE PERMIT TO INSTALL APPROVED: January 7, 2015	SIGNATURE:	
DATE PERMIT VOIDED:	SIGNATURE:	
DATE PERMIT REVOKED:	SIGNATURE:	

Common Abbreviations / Acronyms

	Common Acronyms	Pollutant / Measurement Abbreviations		
AQD	Air Quality Division	BTU	British Thermal Unit	
BACT	Best Available Control Technology	°C	Degrees Celsius	
CAA	Clean Air Act	СО	Carbon Monoxide	
CEM	Continuous Emission Monitoring	dscf	Dry standard cubic foot	
CFR	Code of Federal Regulations	dscm	Dry standard cubic meter	
CO ₂ e	Carbon Dioxide Equivalent	°F	Degrees Fahrenheit	
COM	Continuous Opacity Monitoring	gr	Grains	
EPA	Environmental Protection Agency	Hg	Mercury	
EU	Emission Unit	hr	Hour	
FG	Flexible Group	H ₂ S	Hydrogen Sulfide	
GACS	Gallon of Applied Coating Solids	hp	Horsepower	
GC	General Condition	lb	Pound	
GHGs	Greenhouse Gases	kW	Kilowatt	
HAP	Hazardous Air Pollutant	m	Meter	
HVLP	High Volume Low Pressure *	mg	Milligram	
ID	Identification	mm	Millimeter	
LAER	Lowest Achievable Emission Rate	MM	Million	
MACT	Maximum Achievable Control Technology	MW	Megawatts	
MAERS	Michigan Air Emissions Reporting System	ng	Nanogram	
MAP	Malfunction Abatement Plan	NO _x	Oxides of Nitrogen	
MDEQ	Michigan Department of Environmental Quality (Department)	PM	Particulate Matter	
MSDS	Material Safety Data Sheet	PM10	PM with aerodynamic diameter ≤10 microns	
NESHAP	National Emission Standard for Hazardous Air Pollutants	PM2.5	PM with aerodynamic diameter ≤ 2.5 microns	
NSPS	New Source Performance Standards	pph	Pounds per hour	
NSR	New Source Review	ppm	Parts per million	
PS	Performance Specification	ppmv	Parts per million by volume	
PSD	Prevention of Significant Deterioration	ppmw	Parts per million by weight	
PTE	Permanent Total Enclosure	psia	Pounds per square inch absolute	
PTI	Permit to Install	psig	Pounds per square inch gauge	
RACT	Reasonably Available Control Technology	scf	Standard cubic feet	
ROP	Renewable Operating Permit	sec	Seconds	
SC	Special Condition	SO ₂	Sulfur Dioxide	
SCR	Selective Catalytic Reduction	THC	Total Hydrocarbons	
SRN	State Registration Number	tpy	Tons per year	
TAC	Toxic Air Contaminant	μg	Microgram	
TEQ	Toxicity Equivalence Quotient	VOC	Volatile Organic Compound	
VE	Visible Emissions	yr	Year	

^{*} For High Volume Low Pressure (HVLP) applicators, the pressure measured at the HVLP gun air cap shall not exceed ten (10) pounds per square inch gauge (psig).

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GENERAL CONDITIONS

- 1. The process or process equipment covered by this permit shall not be reconstructed, relocated, or modified, unless a Permit to Install authorizing such action is issued by the Department, except to the extent such action is exempt from the Permit to Install requirements by any applicable rule. (R 336.1201(1))
- 2. If the installation, construction, reconstruction, relocation, or modification of the equipment for which this permit has been approved has not commenced within 18 months, or has been interrupted for 18 months, this permit shall become void unless otherwise authorized by the Department. Furthermore, the permittee or the designated authorized agent shall notify the Department via the Supervisor, Permit Section, Air Quality Division, Michigan Department of Environmental Quality, P.O. Box 30260, Lansing, Michigan 48909-7760, if it is decided not to pursue the installation, construction, reconstruction, relocation, or modification of the equipment allowed by this Permit to Install. (R 336.1201(4))
- 3. If this Permit to Install is issued for a process or process equipment located at a stationary source that is not subject to the Renewable Operating Permit program requirements pursuant to R 336.1210, operation of the process or process equipment is allowed by this permit if the equipment performs in accordance with the terms and conditions of this Permit to Install. (R 336.1201(6)(b))
- 4. The Department may, after notice and opportunity for a hearing, revoke this Permit to Install if evidence indicates the process or process equipment is not performing in accordance with the terms and conditions of this permit or is violating the Department's rules or the Clean Air Act. (R 336.1201(8), Section 5510 of Act 451, PA 1994)
- 5. The terms and conditions of this Permit to Install shall apply to any person or legal entity that now or hereafter owns or operates the process or process equipment at the location authorized by this Permit to Install. If the new owner or operator submits a written request to the Department pursuant to R 336.1219 and the Department approves the request, this permit will be amended to reflect the change of ownership or operational control. The request must include all of the information required by subrules (1)(a), (b), and (c) of R 336.1219 and shall be sent to the District Supervisor, Air Quality Division, Michigan Department of Environmental Quality. (R 336.1219)
- 6. Operation of this equipment shall not result in the emission of an air contaminant which causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property, or which causes unreasonable interference with the comfortable enjoyment of life and property. (R 336.1901)
- 7. The permittee shall provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of a hazardous or toxic air pollutant which continue for more than one hour in excess of any applicable standard or limitation, or emissions of any air contaminant continuing for more than two hours in excess of an applicable standard or limitation, as required in Rule 912, to the Department. The notice shall be provided not later than two business days after start-up, shutdown, or discovery of the abnormal condition or malfunction. Written reports, if required, must be filed with the Department within 10 days after the start-up or shutdown occurred, within 10 days after the abnormal conditions or malfunction has been corrected, or within 30 days of discovery of the abnormal condition or malfunction, whichever is first. The written reports shall include all of the information required in Rule 912(5). (R 336.1912)
- 8. Approval of this permit does not exempt the permittee from complying with any future applicable requirements which may be promulgated under Part 55 of 1994 PA 451, as amended or the Federal Clean Air Act.
- 9. Approval of this permit does not obviate the necessity of obtaining such permits or approvals from other units of government as required by law.
- 10. Operation of this equipment may be subject to other requirements of Part 55 of 1994 PA 451, as amended and the rules promulgated thereunder.

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11. Except as provided in subrules (2) and (3) or unless the special conditions of the Permit to Install include an alternate opacity limit established pursuant to subrule (4) of R 336.1301, the permittee shall not cause or permit to be discharged into the outer air from a process or process equipment a visible emission of density greater than the most stringent of the following. The grading of visible emissions shall be determined in accordance with R 336.1303. (R 336.1301)

- a) A six-minute average of 20 percent opacity, except for one six-minute average per hour of not more than 27 percent opacity.
- b) A visible emission limit specified by an applicable federal new source performance standard.
- c) A visible emission limit specified as a condition of this Permit to Install.
- 12. Collected air contaminants shall be removed as necessary to maintain the equipment at the required operating efficiency. The collection and disposal of air contaminants shall be performed in a manner so as to minimize the introduction of contaminants to the outer air. Transport of collected air contaminants in Priority I and II areas requires the use of material handling methods specified in R 336.1370(2). (R 336.1370)
- 13. The Department may require the permittee to conduct acceptable performance tests, at the permittee's expense, in accordance with R 336.2001 and R 336.2003, under any of the conditions listed in R 336.2001. (R 336.2001)

SPECIAL CONDITIONS

EMISSION UNIT SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Emission Unit ID	Emission Unit Description (Process Equipment & Control Devices)	Flexible Group ID
EUFLUIDBED	Fluid bed granulator used to dry material. Emissions are controlled by an internal bagfilter and HEPA filter collector. (SVFLUIDBED)	FGPRODUCTION
EUACP-3	60 inch film coater used to coat tablets. Emissions are controlled by canister-type dust collector #9. (SV9)	FGPRODUCTION
EUACP-4	60 inch film coater used to coat tablets. Emissions are controlled by canister-type dust collector #5. (SV4)	FGPRODUCTION
EUACP-5	60 inch film coater used to coat tablets. Emissions are controlled by canister-type dust collector #4. (SV5)	FGPRODUCTION
EUACP-6	60 inch film coater used to coat tablets. Emissions are controlled by canister-type dust collector #14. (SV14)	FGPRODUCTION
EUACP-7	60 inch film coater used to coat tablets. Emissions are controlled by canister-type dust collector #18. (SV18)	FGPRODUCTION
EUACP-8	60 inch film coater used to coat tablets. Emissions are controlled by canister-type dust collector #20. (SV20)	FGPRODUCTION
EU300MIXERDC#11	300 Mixer dry powder tumble blender and packaging line 4. Emissions are controlled by canister-type dust collector #11. (SV11)	FGPRODUCTION
EULINE6DC#15	Packaging line 6, where tablet products are packaged into a bottle or container and Corridor E. Emissions are controlled by canister-type dust collector #15. (SV15)	FGPRODUCTION
EUGRANULATOR	Dry powder granulator. Emissions are controlled by canister-type dust collector #16. (SV16)	FGPRODUCTION
EUFLDBDGRANULTR	Fluid bed granulator used to dry material. Emissions are controlled by a canister-type dust collector #22 and HEPA Filter. (SV22)	FGPRODUCTION
EUEQ-13	Tablet compression machine vacuum system. Emissions are controlled by canister-type dust collector #13. (SVEQ-13)	FGPRODUCTION
EUFBG#2	Batch fluid bed granulator where dry product is mixed and coated with a bonding material to form granules, which are then dried. Emissions are controlled by a canister type dust collector (SV21).	FGPRODUCTION
EUDC#12	Area dust collection system for Weigh Rooms. Emissions are controlled by canister-type dust collector #12. (SV12)	FGPRODUCTION
EUDC#23	Area dust collection system for Filling Room. Emissions are controlled by canister-type dust collector #23. (SV23)	FGPRODUCTION
EUDC#24	Area dust collection system for Granulation Suite. Emissions are controlled by canister-type dust collector #24. (SV24)	FGPRODUCTION
EUFBD#3	Fluid Bed Granulator Glatt 500 #1 where dry product is mixed and coated with a bonding material to form granules, which are then dried. Emissions are controlled by canister-type dust collector #25. (SV25)	FGPRODUCTION

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Emission Unit ID	Unit ID Emission Unit Description (Process Equipment & Control Devices)			
EUFBD#4	Fluid Bed Granulator Glatt 500 #2 where dry product is mixed and coated with a bonding material to form granules, which are then dried. Emissions are controlled by canister-type dust collector #26. (SV26)	FGPRODUCTION		
EUDC#13	Area dust collection system for 300 Mixer and Line 4 area. Emissions are controlled by cartridge dust collector #13. (SV13)	FGPRODUCTION		
EUEQ#38	Area dust collection system for Line 6 and Corridor E located in the Freezer Mechanical Space. Emissions are controlled by cartridge dust collector #38. (SV38)	FGPRODUCTION		
EUEQ#12	JEQ#12 Area dust collection system for the manufacturing area located in the Boiler Mechanical Room. Emissions are controlled by cartridge dust collector #12. (EQ12)			
EUEQ#45	Area dust collection system for the South Expansion. Emissions are controlled by cartridge dust collector #45. (SV45)	FGPRODUCTION		
Changes to the equipment described in this table are subject to the requirements of R 336.1201, except as				

allowed by R 336.1278 to R 336.1290.

FLEXIBLE GROUP SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Flexible Group ID	Flexible Group Description	Associated Emission Unit IDs
FGPRODUCTION	Solid pharmaceutical and nutritional materials manufacturing.	EUFLUIDBED, EUACP-3, EUACP-4, EUACP-5, EUACP-6, EUACP-7, EUACP-8, EU300MIXERDC#11, EULINE6DC#15, EUGRANULATOR, EUFLDBDGRANULTR, EUEQ-13, EUFBG#2, EUDC#12, EUDC#23, EUDC#24, EUFBD#3, EUFBD#4, EUDC#13, EUEQ#38, EUEQ#12, EUEQ#45

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The following conditions apply to: FGPRODUCTION

<u>DESCRIPTION:</u> Solid pharmaceutical and nutritional materials manufacturing

Emission Units: EUFLUIDBED, EUACP-3, EUACP-4, EUACP-5, EUACP-6, EUACP-7, EUACP-8, EU300MIXERDC#11, EULINE6DC#15, EUGRANULATOR, EUFLDBDGRANULTR, EUEQ-13, EUFBG#2, EUDC#12, EUDC#23, EUDC#24, EUFBD#3, EUFBD#4, EUDC#13, EUEQ#38, EUEQ#12, EUEQ#45

POLLUTION CONTROL EQUIPMENT: Various dust collectors

I. EMISSION LIMITS

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Testing / Monitoring Method	Underlying Applicable Requirements	
1. PM	0.0000165 pph ¹	Test Protocol*	EUFLUIDBED	GC 13	R 336.1225	
2. PM	0.17 pph ¹	Test Protocol*	EUACP-3	GC 13	R 336.1225	
3. PM	0.018 pph ¹	Test Protocol*	EUACP-4	GC 13	R 336.1225	
4. PM	0.018 pph ¹	Test Protocol*	EUACP-5	GC 13	R 336.1225	
5. PM	0.018 pph ¹	Test Protocol*	EUACP-6	GC 13	R 336.1225	
6. PM	0.018 pph ¹	Test Protocol*	EUACP-7	GC 13	R 336.1225	
7. PM	0.018 pph ¹	Test Protocol*	EUACP-8	GC 13	R 336.1225	
8. PM	0.018 pph ¹	Test Protocol*	EU300MIXERDC#11	GC 13	R 336.1225	
9. PM	0.0108 pph ¹	Test Protocol*	EULINE6DC#15	GC 13	R 336.1225	
10. PM	0.0108 pph ¹	Test Protocol*	EUGRANULATOR	GC 13	R 336.1225	
11. PM	0.00000477 pph ¹	Test Protocol*	EUFLDBDGRANULTR	GC 13	R 336.1225	
12. PM	0.56 pph ¹	Test Protocol*	EUEQ-13	GC 13	R 336.1225	
13. PM	0.0265 pph ¹	Test Protocol*	EUFBG#2	GC 13	R 336.1225	
14. PM	0.0108 pph ¹	Test Protocol*	EUDC#12	GC 13	R 336.1225	
15. PM	0.0054 pph ¹	Test Protocol*	EUDC#23	GC 13	R 336.1225	
16. PM	0.0144 pph ¹	Test Protocol*	EUDC#24	GC 13	R 336.1225	
17. PM	0.025 pph ¹	Test Protocol*	EUFBD#3	GC 13	R 336.1225	
18. PM	0.025 pph ¹	Test Protocol*	EUFBD#4	GC 13	R 336.1225	
19. PM	0.0026 pph ¹	Test Protocol*	EUDC#13	GC 13	R 336.1225	
20. PM	0.0032 pph ¹	Test Protocol*	EUEQ#38	GC 13	R 336.1225	
21. PM	0.0072 pph ¹	Test Protocol*	EUEQ#12	GC 13	R 336.1225	
22. PM	0.0037 pph ¹	Test Protocol*	EUEQ#45	GC 13	R 336.1225	
*Test Protocol shall specify averaging time						

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II. MATERIAL LIMITS

1. The permittee shall limit the usage in FGPRODUCTION of each raw material that is a toxic air contaminant (TAC), as defined in R 336.1120, 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 in equation 1 below. For each raw material that is a TAC with an AQD established screening level, the allowable concentration shall be the AQD screening level. For each raw material listed in the table below, the allowable concentration listed in the table below, the permittee may use the AQD screening level instead of the allowable concentration listed in the table below. For raw materials that are TACs not listed below for which there is no AQD screening level, the allowable concentration shall be determined according to Rules 231 and 232 (R 336.1231 and R 336.1232), except that the allowable concentration shall not exceed 15 μg/m³ on an annual average. For each raw material, the predicted ambient impact used shall have the same averaging time as the allowable concentration.¹ (R 336.1225)

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^A)

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 = $54.34 \,\mu\text{g/m}^3$ 3 hour PAI = $36.48 \,\mu\text{g/m}^3$ 8 hour PAI = $31.11 \,\mu\text{g/m}^3$ 24 hour PAI = $16.75 \,\mu\text{g/m}^3$ Annual PAI = $2.61 \,\mu\text{g/m}^3$

Raw Material	Allowable Concentration (µg/m³)	Concentration Averaging Time	Raw Material	Allowable Concentration (µg/m³)	Concentration Averaging Time
Acetaminophen	15		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		IM Citrucel Prep Granulation 34818	愀.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.

III. PROCESS/OPERATIONAL RESTRICTIONS

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IV. DESIGN/EQUIPMENT PARAMETERS

1. The permittee shall not operate the following emission units 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. (R 336.1225, R 336.1331, R 336.1910)

	Emission Unit	Associated Control Equipment
a.	EUFLUIDBED	internal bagfilter and HEPA filter collector
b.	EUACP-3	canister-type dust collector #9
C.	EUACP-4	canister-type dust collector #5
d.	EUACP-5	canister-type dust collector #4
e.	EUACP-6	canister-type dust collector #14
f.	EUACP-7	canister-type dust collector #18
g.	EUACP-8	canister-type dust collector #20
h.	EU300MIXERDC#11	canister-type dust collector #11
i.	EULINE6DC#15	canister-type dust collector #15
j.	EUGRANULATOR	canister-type dust collector #16
k.	EUFLDBDGRANULTR	canister-type dust collector #22 and HEPA filter collector
I.	EUEQ-13	canister-type dust collector #13
m.	EUFBG#2	canister-type dust collector #21
n.	EUDC#12	canister-type dust collector #12
0.	EUDC#23	canister-type dust collector #23
p.	EUDC#24	canister-type dust collector #24
q.	EUFBD#3	canister-type dust collector #32
r.	EUFBD#4	canister-type dust collector #33
s.	EUDC#13	cartridge dust collector #13
t.	EUEQ#38	cartridge dust collector #38
u.	EUEQ#12	cartridge dust collector #12
٧.	EUEQ#45	cartridge dust collector #45

2. The permittee shall equip and maintain each dust collector with a differential pressure monitoring device. (R 336.1225, R 336.1331, R 336.1910)

V. TESTING/SAMPLING

Records shall be maintained on file for a period of five years. (R 336.1201(3))

NA

VI. MONITORING/RECORDKEEPING

Records shall be maintained on file for a period of five years. (R 336.1201(3))

- 1. The permittee shall keep, in a satisfactory manner, 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. (R 336.1225, R 336.1331, R 336.1910)
- 2. The permittee shall complete all required calculations in a format acceptable to the AQD District Supervisor by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition.¹ (R 336.1225)
- 3. The permittee shall keep, in a satisfactory manner, monthly production and material usage records for FGPRODUCTION to show compliance with the material usage limits in SC II.1 on file at the facility and make them available to the Department upon request. (R 336.1225)

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VII. REPORTING

NA

VIII. STACK/VENT 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)	Underlying Applicable Requirements
1. SVFLUIDBED ^A	20	36	R 336.1225, 40 CFR 52.21 (c) & (d)
2. SV4	16	48	R 336.1225, 40 CFR 52.21 (c) & (d)
3. SV5	16	50.7	R 336.1225, 40 CFR 52.21 (c) & (d)
4. SV9	18	48	R 336.1225, 40 CFR 52.21 (c) & (d)
5. SV11 ^A	12 x 24	18	R 336.1225, 40 CFR 52.21 (c) & (d)
6. SVEQ-13	10	48	R 336.1225, 40 CFR 52.21 (c) & (d)
7. SV14	15	18.5	R 336.1225, 40 CFR 52.21 (c) & (d)
8. SV15 ^A	10 x 16	10	R 336.1225, 40 CFR 52.21 (c) & (d)
9. SV16	10	40	R 336.1225, 40 CFR 52.21 (c) & (d)
10. SV18	16	46	R 336.1225, 40 CFR 52.21 (c) & (d)
11. SV20	15	18.5	R 336.1225, 40 CFR 52.21 (c) & (d)
12. SV21 ^A	16	38	R 336.1225, 40 CFR 52.21 (c) & (d)
13. SV22	12	51	R 336.1225, 40 CFR 52.21 (c) & (d)
14. SV12	16	51	R 336.1225, 40 CFR 52.21 (c) & (d)
15. SV23	16	75	R 336.1225, 40 CFR 52.21 (c) & (d)
16. SV24	24	75	R 336.1225, 40 CFR 52.21 (c) & (d)
17. SV25	24	75	R 336.1225, 40 CFR 52.21 (c) & (d)
18. SV26	24	75	R 336.1225, 40 CFR 52.21 (c) & (d)
19. EQ12	12 x 12	48	R 336.1225, 40 CFR 52.21 (c) & (d)
20. SV13 A	4	16.5	R 336.1225, 40 CFR 52.21 (c) & (d)
21. SV38	6	22	R 336.1225, 40 CFR 52.21 (c) & (d)
22. SV45	8	75	R 336.1225, 40 CFR 52.21 (c) & (d)
A These stacks do no	ot exhaust vertically upward	s to the ambient air.	

IX. OTHER REQUIREMENTS

NA

Footnotes: ¹This condition is state only enforceable and was established pursuant to Rule 201(1)(b).