MISSOURI AIR CONSERVATION COMMISSION

PERMIT TO CONSTRUCT

Under the authority of RSMo 643 and the Federal Clean Air Act the applicant is authorized to construct the air contaminant source(s) described below, in accordance with the laws, rules and conditions as set forth herein.

Permit Number: 052018-002
Project Number: 2017-12-010
Installation Number: 183-0263

Parent Company: Valeant Pharmaceuticals/Bausch & Lomb
Parent Company Address: 400 Sommerset Corporate Blvd, Bridgewater, NJ 08807

Installation Name: Synergetics, Inc.
Installation Address: 3845 Corporate Centre Drive, O'Fallon, MO 63368
Location Information: St. Charles County (Land Grant 1669)

Application for Authority to Construct was made for:
The operation of a previously unpermitted manufacturing facility. This review was conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, Construction Permits Required.

☐ Standard Conditions (on reverse) are applicable to this permit.
☑ Standard Conditions (on reverse) and Special Conditions are applicable to this permit.

Prepared by
Ryan Schott
New Source Review Unit

Director or Designee
Department of Natural Resources

MAY 03 2018
Effective Date
STANDARD CONDITIONS:

Permission to construct may be revoked if you fail to begin construction or modification within two years from the effective date of this permit. Permittee should notify the Enforcement and Compliance Section of the Air Pollution Control Program if construction or modification is not started within two years after the effective date of this permit, or if construction or modification is suspended for one year or more.

You will be in violation of 10 CSR 10-6.060 if you fail to adhere to the specifications and conditions listed in your application, this permit and the project review. In the event that there is a discrepancy between the permit application and this permit, the conditions of this permit shall take precedence. Specifically, all air contaminant control devices shall be operated and maintained as specified in the application, associated plans and specifications.

You must notify the Enforcement and Compliance Section of the Department's Air Pollution Control Program of the anticipated date of startup of this (these) air contaminant source(s). The information must be made available within 30 days of actual startup. Also, you must notify the Department's regional office responsible for the area within which you are located within 15 days after the actual startup of this (these) air contaminant source(s).

A copy of the permit application and this permit and permit review shall be kept at the installation address and shall be made available to Department's personnel upon request.

You may appeal this permit or any of the listed special conditions to the Administrative Hearing Commission (AHC), P.O. Box 1557, Jefferson City, MO 65102, as provided in RSMo 643.075.6 and 621.250.3. If you choose to appeal, you must file a petition with the AHC within 30 days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed. If it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the AHC.

If you choose not to appeal, this certificate, the project review and your application and associated correspondence constitutes your permit to construct. The permit allows you to construct and operate your air contaminant source(s), but in no way relieves you of your obligation to comply with all applicable provisions of the Missouri Air Conservation Law, regulations of the Missouri Department of Natural Resources and other applicable federal, state and local laws and ordinances.

The Air Pollution Control Program invites your questions regarding this air pollution permit. Please contact the Construction Permit Unit using the contact information below.

Contact Information:
Missouri Department of Natural Resources
Air Pollution Control Program
P.O. Box 176
Jefferson City, MO 65102-0176
(573) 751-4817

The regional office information can be found at the following website:
http://dnr.mo.gov/regions/
SPECIAL CONDITIONS:
The permittee is authorized to construct and operate subject to the following special conditions:

The special conditions listed in this permit were included based on the authority granted the Missouri Air Pollution Control Program by the Missouri Air Conservation Law (specifically 643.075) and by the Missouri Rules listed in Title 10, Division 10 of the Code of State Regulations (specifically 10 CSR 10-6.060). For specific details regarding conditions, see 10 CSR 10-6.060 paragraph (12)(A)10. “Conditions required by permitting authority.”

Synergetics, Inc.
St. Charles County (Land Grant 1669)

1. Operational Limitation – Spray Coating
   A. Synergetics, Inc. shall spray no more than 4,380 gallons of coatings in the paint booth (EP-01) in any consecutive 12-month period.
   
   B. Synergetics, Inc. shall develop and use forms to demonstrate compliance with Special Condition 1.A. The forms shall contain, at a minimum, the following information:
      1) Installation name & ID
      2) Permit number
      3) Current month & 12-month date range
      4) Monthly throughput of coating sprayed
      5) 12-month rolling total throughput of coating sprayed

2. Capture & Control Device Requirement – Paint Booth & Fabric Filters
   A. Synergetics, Inc. shall capture and control emissions from spray coating operations (EP-01) using an enclosed paint booth and fabric filters, as specified in the permit application.
   
   B. Synergetics, Inc. shall use visual indicators, such as negative pressure gauges, streamers, talc puff tests, etc. at the booth openings to indicate that the flow of air is inwards toward the filters. Synergetics, Inc. shall perform a visual indicator check at least once every calendar month while the paint booth is in operation. The results of the visual indicator check shall be indicated in a log.
   
   C. The filters shall be operated and maintained in accordance with the manufacturer’s specifications.

   D. The paint booth shall be equipped with a gauge or meter, which indicates the pressure drop across the control device. This gauge or meter shall be located such that Department of Natural Resources’ employees may easily observe it. Synergetics, Inc. shall monitor and record the operating pressure drop across the filter at least once every 24 hours while coatings are being applied. The operating pressure drop shall be maintained within the design conditions specified by the manufacturer’s performance warranty.
SPECIAL CONDITIONS:
The permittee is authorized to construct and operate subject to the following special conditions:

E. Replacement filters shall be kept on hand at all times. The filters shall be made of fibers appropriate for operating conditions expected to occur (i.e. temperature limits, acidic and alkali resistance, and abrasion resistance).

F. Synergetics, Inc. shall maintain a copy of the filter manufacturer's performance warranty on site.

G. Synergetics, Inc. shall maintain an operating and maintenance log for the filters, which shall include the following:
   1) Incidents of malfunction, with impact on emissions (tons), duration of event, probable cause, and corrective actions; and
   2) Maintenance activities, with inspection schedule, repair actions, and replacements, etc.

3. Capture & Control Device Requirement – Sand Blasting Booth & Fabric Filters
   A. Synergetics, Inc. shall capture and control emissions from the three sandblasters using enclosed booths and integrated fabric filters, as specified in the permit application.

   B. The filters shall be operated and maintained in accordance with the manufacturer's specifications.

   C. Each integrated filter shall be equipped with a gauge or meter, which indicates the pressure drop across the control device. Sandblasters 1 & 2, however, also vent to a baghouse; therefore, the baghouse may be equipped with a gauge or meter, which indicates its pressure drop, instead of the two individual sandblasters.

   D. These gauges or meters shall be located such that Department of Natural Resources' employees may easily observe them. Synergetics, Inc. shall monitor and record the operating pressure drop across the control devices at least once every 24 hours when sandblasting is occurring. The operating pressure drop shall be maintained within the design conditions specified by the manufacturers' performance warranties.

   E. Replacement filters shall be kept on and at all times. The filters shall be made of fibers appropriate for operating conditions expected to occur (i.e. temperature limits, acidic and alkali resistance, and abrasion resistance).

   F. Synergetics, Inc. shall maintain a copy of the baghouse/filter manufacturers' performance warranties on site.
SPECIAL CONDITIONS:
The permittee is authorized to construct and operate subject to the following special conditions:

G. Synergetics, Inc. shall maintain an operating and maintenance log for the baghouse and filters, which shall include the following:
   1) Incidents of malfunction, with impact on emissions (tons), duration of event, probable cause, and corrective actions; and
   2) Maintenance activities, with inspection schedule, repair actions, and replacements, etc.

4. Record Keeping and Reporting Requirements
   A. Synergetics, Inc. shall maintain all records required by this permit for not less than five years and shall make them available immediately to any Missouri Department of Natural Resources' personnel upon request. These records shall include SDS for all materials used.

   B. Synergetics, Inc. shall report to the Air Pollution Control Program's Compliance/Enforcement Section, by mail at P.O. Box 176, Jefferson City, MO 65102 or by email at aircompliancereporting@dnr.mo.gov, no later than 10 days after the end of the month during which any record required by this permit shows an exceedance of a limitation imposed by this permit.
REVIEW SUMMARY

• Synergetics, Inc. has applied for authority to operate a previously unpermitted manufacturing facility.

• The application was deemed complete on December 15, 2017.

• HAP emissions are expected from the proposed equipment. HAPs of concern from this process include dimethyl phthalate.

• None of the New Source Performance Standards apply to the installation. None of the currently promulgated MACT regulations apply to the proposed equipment.

• 10 CSR 10-5.330 Control of Emissions from Industrial Surface Coating Operations applies to the installation; however, because the coatings applied to the metal parts are electric-insulating, the paint booth is not required to meet the VOC limits set by this rule.

• Paint booth filters and sand blasting filters are being used to control the particulate emissions from the equipment in this permit.

• This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, Construction Permits Required. Potential VOC and HAP emissions are indirectly limited below de minimis levels by a spray coating throughput limit. Potential emissions of all other pollutants are below their respective de minimis levels and SMALs.

• This installation is located in St. Charles County, a nonattainment area for the 8-hour ozone standard (2008) and the PM$_{2.5}$ standard (1997) and an attainment/unclassifiable area for all other criteria pollutants.
• This installation is not on the List of Named Installations found in 10 CSR 10-6.020(3)(B), Table 2. The installation's major source level is 100 tons per year for PM$_{2.5}$, NO$_x$ & VOC and 250 tons per year for all other pollutants. Fugitive emissions are not counted toward major source applicability.

• Emissions testing is not required for the equipment as a part of this permit. Testing may be required as part of other state, federal or applicable rules.

• No Operating Permit is required for this installation.

• Approval of this permit is recommended with special conditions.

INSTALLATION/PROJECT DESCRIPTION

Synergetics, Inc. manufactures ophthalmic and neurological medical devices, including one time use items and associated electromechanical interface devices. Upon purchase of the Synergetics, Inc. facility by Valeant Pharmaceuticals/Bausch & Lomb, it was discovered that no construction permits or operating permits had been applied for prior to the installation and operation of the manufacturing equipment. Valeant Pharmaceuticals/Bausch & Lomb has submitted a construction permit application to the Air Pollution Control Program in order to receive a remedial permit for the existing equipment at the facility.

Current facility operations include a _____ gallon per hour spray painting operation, silver and nickel electroless plating tanks, a parts washer, a passivation process, three _____ pound per hour sand blasting units, and three _____ pound per hour polishing wheels. Also at the facility are several natural gas fired space heaters with heat inputs totaling ____ MMBtu/hr.

Synergetics, Inc. has requested to keep the process design rates, control efficiencies, and specific coating formulas confidential per Missouri State Rules 10 CSR 10-6.210, Confidential Information. This is the public version of the permit. A confidential version is available under Project No. 2017-12-029.

EMISSIONS/CONTROLS EVALUATION

Synergetics, Inc. is capable of spraying up to _____ gallons of coatings per hour; however, operations were voluntarily limited to 0.5 gallons per hour (4,380 gallons per year) to keep potential VOC and HAP emissions below de minimis levels and represent an actual maximum operating rate. VOC and HAP emissions from spray coating were calculated using mass balances. VOC content and constituent HAP percentages were taken from the coating SDS and assumed to equal to the highest percentage if a range is listed. It was assumed that the coating with the highest VOC/HAP emissions was used exclusively in the paint booth. It was also assumed that the paint to solvent ratio is ___, which is the manufacturer’s recommended viscosity adjustment value.
PM, PM$_{10}$, and PM$_{2.5}$ emissions from the spray coating operation were calculated using methods taken from the document – *Painting Basics and Emission Calculations for TCEQ Air Quality Permit Applications* (November 2012). The solids transfer efficiency of the air atomized spray gun was conservatively taken to be 1111. The fallout fractions, or emitted particulate size distributions, for PM$_{10}$ and PM$_{2.5}$ were taken to be 1111 and 1111, respectively. The solids content was taken from the coating SDS and assumed to equal the highest value if a range was listed. The enclosed paint booth is under negative pressure; therefore it was given a capture efficiency of 100% for particulate matter. The paint booth filters are rated with a 1111 removal efficiency for particles greater than 1111 µm; therefore, a control efficiency of 1111 was given to the filters for PM and PM$_{10}$, while the control efficiency for PM$_{2.5}$ was conservatively assumed to be 1111.

Potential emissions from silver plating and electroless nickel plating were calculated using the equations and values found in the EPA document *AP-42 Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources*, Fifth Edition Section 12.20 *Electroplating* (July 1996).

Potential VOC and HAP emissions from evaporative losses that occur during parts washing, passivation, and disposable chemical usage were calculated using mass balances. The maximum usage rate for each chemical was taken to be twice the actual usage rate of that chemical in the 2016 calendar year. This is a conservative estimate due to the operating rates of the processes and the historical daily chemical usage rate. VOC content and constituent HAP percentages were taken from the solvent SDS and assumed to equal the highest percentage if a range is listed. Some of the passivation chemicals contain small amounts of chromium (VI) compounds, cyanide compounds, and hydrogen fluoride; however, these constituents bond to the surface to which they are applied and become part of the coating or remain dissolved in solution, which means they are not emitted to the air. Potential chromium (VI), cyanide, and hydrogen fluoride emissions were assumed to be negligible and were not evaluated as part of this project.

Potential particulate emissions from the three sand blasters were calculated using emission factors taken from AP-42 Section 13.2.6 *Abrasive Blasting* (October 1997). All three sand blasters are controlled by an integrated fabric filter, and two of them are also vented to a baghouse; therefore, the controlled emission factors were used.

Potential particulate emissions from the three polishing wheels were calculated using emission factors taken from the EPA’s emission factor database, WebFIRE, under SCC 3-04-003-40.

Potential emissions from the space heaters were calculated using emission factors taken from AP-42 Section 1.4 *Natural Gas Combustion* (July 1998).

The following table provides an emissions summary for this project. Because the facility has never received a construction permit, existing potential emissions have not been evaluated. Because the facility has never submitted an EIQ, existing actual emission data does not exist. Potential emissions of the project represent the potential of the
equipment, assuming continuous operation (8,760 hours per year). New installation conditioned potential emissions account for a voluntary spray coating throughput limit, which indirectly limits VOC and HAP emissions below de minimis levels.

Table 1: Emissions Summary (tons per year)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PM</td>
<td>25.0</td>
<td>N/D</td>
<td>N/D</td>
<td>16.71</td>
<td>4.71</td>
</tr>
<tr>
<td>PM$_{10}$</td>
<td>15.0</td>
<td>N/D</td>
<td>N/D</td>
<td>2.67</td>
<td>1.95</td>
</tr>
<tr>
<td>PM$_{2.5}$</td>
<td>10.0</td>
<td>N/D</td>
<td>N/D</td>
<td>2.27</td>
<td>1.87</td>
</tr>
<tr>
<td>SO$_x$</td>
<td>40.0</td>
<td>N/D</td>
<td>N/D</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>NO$_x$</td>
<td>40.0</td>
<td>N/D</td>
<td>N/D</td>
<td>1.50</td>
<td>1.50</td>
</tr>
<tr>
<td>VOC</td>
<td>40.0</td>
<td>N/D</td>
<td>N/D</td>
<td>82.96</td>
<td>16.81</td>
</tr>
<tr>
<td>CO</td>
<td>100.0</td>
<td>N/D</td>
<td>N/D</td>
<td>1.26</td>
<td>1.26</td>
</tr>
<tr>
<td>Dimethyl Phthalate</td>
<td>10.0 / 10</td>
<td>N/D</td>
<td>N/D</td>
<td>52.56</td>
<td>9.54</td>
</tr>
<tr>
<td>*Other HAPs</td>
<td>N/A</td>
<td>N/D</td>
<td>N/D</td>
<td>0.46</td>
<td>0.46</td>
</tr>
<tr>
<td>Total HAPs</td>
<td>25.0</td>
<td>N/D</td>
<td>N/D</td>
<td>53.02</td>
<td>10.00</td>
</tr>
</tbody>
</table>

SMAL = Screening Model Action Level
N/D = Not Determined
*Other HAPs represent the numerous individual solvent and combustion HAPs emitted in trace amounts, each below its respective SMAL

PERMIT RULE APPLICABILITY

This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, Construction Permits Required. Potential VOC and HAP emissions are indirectly limited below de minimis levels by a spray coating throughput limit. Potential emissions of all other pollutants are below their respective de minimis levels and SMALs.

APPLICABLE REQUIREMENTS

Synergetics, Inc. shall comply with the following applicable requirements. The Missouri Air Conservation Laws and Regulations should be consulted for specific record keeping, monitoring, and reporting requirements. Compliance with these emission standards, based on information submitted in the application, has been verified at the time this application was approved.
GENERAL REQUIREMENTS

Start-Up, Shutdown, and Malfunction Conditions, 10 CSR 10-6.050

- Submission of Emission Data, Emission Fees and Process Information, 10 CSR 10-6.110
  ➢ Per 10 CSR 10-6.110(4)(B)2.B(II) and (4)(B)2.C(II) a full EIQ is required for the first full calendar year the equipment (or modifications) approved by this permit are in operation.

- Restriction of Emission of Odors, 10 CSR 10-6.165

- Restriction of Particulate Matter to the Ambient Air Beyond the Premises of Origin, 10 CSR 10-6.170

- Restriction of Emission of Visible Air Contaminants, 10 CSR 10-6.220

SPECIFIC REQUIREMENTS

- Control of Emissions from Industrial Surface Coating Operations, 10 CSR 10-5.330

STAFF RECOMMENDATION

On the basis of this review conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, Construction Permits Required, it is recommended that this permit be granted with special conditions.

PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated November 30, 2017, received December 5, 2017, designating Valeant Pharmaceuticals/Bausch & Lomb as the owner and operator of the installation.
APPENDIX A

Abbreviations and Acronyms

% .............. percent
°F .............. degrees Fahrenheit
acfm ........... actual cubic feet per minute
BACT .......... Best Available Control Technology
BMPs .......... Best Management Practices
Btu ............ British thermal unit
CAM .......... Compliance Assurance Monitoring
CAS ........... Chemical Abstracts Service
CEMS ........ Continuous Emission Monitor System
CFR .......... Code of Federal Regulations
CO .......... carbon monoxide
CO₂ .......... carbon dioxide
CO₂e .......... carbon dioxide equivalent
COMS .......... Continuous Opacity Monitoring System
CSR .......... Code of State Regulations
dscf .......... dry standard cubic feet
EIQ .......... Emission Inventory Questionnaire
EP .......... Emission Point
EPA .......... Environmental Protection Agency
EU .......... Emission Unit
fps .......... feet per second
ft ............ feet
GACT .......... Generally Available Control Technology
GHG .......... Greenhouse Gas
gpm .......... gallons per minute
gr .......... grains
GWP .......... Global Warming Potential
HAP .......... Hazardous Air Pollutant
hr ........... hour
hp .......... horsepower
lb .......... pound
lbs/hr ......... pounds per hour
MACT .......... Maximum Achievable Control Technology
µg/m³ .......... micrograms per cubic meter
m/s .......... meters per second
Mgal ..........1,000 gallons
MW ........... megawatt
MHDR .......... maximum hourly design rate
MMBtu ....... Million British thermal units
MMCF ......... million cubic feet
MSDS .......... Material Safety Data Sheet
NAAQS .......... National Ambient Air Quality Standards
NESHAPs .......... National Emissions Standards for Hazardous Air Pollutants
NOₓ .......... nitrogen oxides
NSPS .......... New Source Performance Standards
NSR .......... New Source Review
PM .......... particulate matter
PM₂,₅ .......... particulate matter less than 2.5 microns in aerodynamic diameter
PM₁₀ .......... particulate matter less than 10 microns in aerodynamic diameter
ppm .......... parts per million
PSD .......... Prevention of Significant Deterioration
PTE .......... potential to emit
RACT .......... Reasonable Available Control Technology
RAL .......... Risk Assessment Level
SCC .......... Source Classification Code
scfm .......... standard cubic feet per minute
SDS .......... Safety Data Sheet
SIC .......... Standard Industrial Classification
SIP .......... State Implementation Plan
SMAL .......... Screening Model Action Levels
SOₓ .......... sulfur oxides
SO₂ .......... sulfur dioxide
tph .......... tons per hour
ty .......... tons per year
VMT .......... vehicle miles traveled
VOC .......... Volatile Organic Compound
MAY 03 2018

Ms. Julie Miller  
EH&S Specialist  
Synergetics, Inc.  
3365 Tree Court Industrial Blvd  
St. Louis, MO 63122

RE: New Source Review Permit - Project Number: 2017-12-010

Dear Ms. Miller:

Enclosed with this letter is your permit to construct. Please study it carefully and refer to Appendix A for a list of common abbreviations and acronyms used in the permit. Also, note the special conditions on the accompanying pages. The document entitled, "Review of Application for Authority to Construct," is part of the permit and should be kept with this permit in your files. Operation in accordance with these conditions and your new source review permit application is necessary for continued compliance. The reverse side of your permit certificate has important information concerning standard permit conditions and your rights and obligations under the laws and regulations of the State of Missouri.

This permit may include requirements with which you may not be familiar. If you would like the department to meet with you to discuss how to understand and satisfy the requirements contained in this permit, an appointment referred to as a Compliance Assistance Visit (CAV) can be set up with you. To request a CAV, please contact your local regional office or fill out an online request. The regional office contact information can be found at the following website: http://dnr.mo.gov/regions/. The online CAV request can be found at http://dnr.mo.gov/cav/compliance.htm.

If you were adversely affected by this permit decision, you may be entitled to pursue an appeal before the administrative hearing commission pursuant to Sections 621.250 and 643.075.6 RSMo. To appeal, you must file a petition with the administrative hearing commission within thirty days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed; if it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the administrative hearing commission, whose contact information is: Administrative Hearing Commission, United States Post Office Building, 131 West High Street, Third Floor, P.O. Box 1557, Jefferson City, Missouri 65102, phone: 573-751-2422, fax: 573-751-5018, website: www.oa.mo.gov/ahc.
If you have any questions regarding this permit, please do not hesitate to contact Ryan Schott, at the Department of Natural Resources’ Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102 or at (573) 751-4817. Thank you for your attention to this matter.

Sincerely,

AIR POLLUTION CONTROL PROGRAM

Susan Heckenkamp
New Source Review Unit Chief

Enclosures

c: St. Louis Regional Office
   PAMS File: 2017-12-010

Permit Number: 52018-002