

**1. PERMITTEE**

Bausch & Lomb, Inc.  
8500 Hidden River Parkway  
Tampa, FL 33637

**2. PERMITTING AUTHORITY**

Environmental Protection Commission of Hillsborough County  
3629 Queen Palm Dr.  
Tampa, FL 33619

**3. PROJECT**

Air Permit No. 0570459-013-AF  
Federally Enforceable State Operation Permit (FESOP)

In order to provide operational flexibility, as requested by the permittee, this permit removes the material usage limit and replaces it with a facility-wide limit on the VOC PTE. The facility-wide potential VOC emissions are limited to 45 tons/year.

**4. NOTICE AND PUBLICATION**

The EPCHC distributed a draft minor FESOP package on January 25, 2018. The applicant published the Public Notice in La Gaceta on February 2, 2018. The EPCHC received the proof of publication on February 5, 2018. No requests for administrative hearings or requests for extensions of time to file a petition for administrative hearing were received.

**COMMENTS**

**Applicant**

On January 26, 2018, the EPCHC received comments via email from Mitchell Hait, Ph.D., P.E. on behalf of the applicant. The following summarizes the comments and the EPCHC's responses.

1. In Section 2 of the Technical Evaluation, it says NA under the Federal NSPS Provisions section. However, 40 CFR 60 Subpart IIII should have been listed under this heading because the facility is subject to this NSPS.

*Response:* EPCHC staff acknowledges that 40 CFR 60 Subpart IIII should have been listed in this Section. However, in Section I., General Information, Process Description, of the Draft and Final Permits, it states that the engines are subject to either 40 CFR 60 Subpart IIII or 40 CFR 63 Subpart ZZZZ. Therefore, no changes are required in the Final Permit.

2. Specific Condition No. A.3.F) states "Monthly total of material recycled (optional)". We believe it is better to have this item listed as "monthly total of material recycled or disposed of as waste (optional)".

*Response:* After further review, EPCHC staff agrees that the facility can take credit for the amount of material disposed of if it is collected and disposed offsite. The condition is changed as follows;

**From:**

A.3.F) Monthly total of material recycled (optional)

**To:**

A.3.F) Monthly total of material recycled or collected and disposed offsite (optional)

3. Specific Condition No. A.3.L) states "Safety data sheets (SDS) for each material used, in order to verify the VOC and HAP content, as applicable, of each material". However, some of the information Bausch & Lomb uses is not on the SDS – for example, for the acetic acid (Spor-Klenz), that information is on the

## FINAL DETERMINATION

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Certificate of Manufacture / Analysis. Bausch & Lomb recommends changing the language to “SDS, other manufacturer provided information, or standard Chemistry or Engineering references” to provide operational flexibility.

*Response:* EPCHC staff agrees that manufacturer’s information may be used to document the VOC and/or HAP contents of the materials. However, each material used at the facility should have specific manufacturer’s supplied information detailing the composition of the material, rather than relying on generic chemistry or engineering references. Therefore, the condition is changed as follows;

**From:**

A.3.L) Safety data sheets (SDS) for each material used, in order to verify the VOC and HAP content, as applicable, of each material.

**To:**

A.3.L) Safety data sheets (SDS) or other certified manufacturer provided information in order to verify the VOC and HAP content, as applicable, of each material.

## 5. CONCLUSION

The final action of the Department is to issue the permit with the minor changes as described above.

**COMMISSION**

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**PERMITTEE**

Bausch & Lomb, Inc.  
8500 Hidden River Parkway  
Tampa, FL 33637

*Authorized Representative:*

David Dufort, Director Site Operations

Project No. 0570459-013-AF

Federally Enforceable State Operation Permit

Effective Date: February 19, 2018

Renewal Application Due Date: March 30, 2020

Expiration Date: May 29, 2020

Pharmaceutical Formulating and Packaging Facility  
Hillsborough County, Florida

**PROJECT**

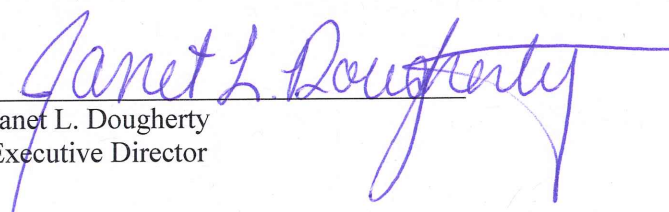
This is the final Federally Enforceable State Operation Permit, which authorizes the operation of Bausch & Lomb, Inc., a pharmaceutical formulating and packaging facility (Standard Industrial Classification Code No. 2834 – Pharmaceutical Preparations). The facility is located in Hillsborough County at 8500 Hidden River Parkway, Tampa, FL 33637. The UTM coordinates of the new facility are Zone 17, 365.97 km East, and 3106.21 km North.

This final permit is organized into the following sections: Section 1 (General Information); Section 2 (Administrative Requirements); Section 3 (Emissions Unit Specific Conditions); and Section 4 (Appendices). Because of the technical nature of the project, the permit contains numerous acronyms and abbreviations, which are defined in Appendix A of Section 4 of this permit.

Upon issuance of this final permit, any party to this permitting decision (order) has the right to seek judicial review of it under Section 120.68, F.S., by filing a notice of appeal under Rule 9.110 of the Florida Rules of Appellate Procedure with the Legal Department of the EPC at 3629 Queen Palm Drive, Tampa, Florida 33619, and by filing a copy of the notice of appeal accompanied by the applicable filing fees with the appropriate District Court of Appeal. The notice must be filed within 30 days after this order is filed with the clerk of the Department.

Executed in Tampa, Florida.

ENVIRONMENTAL PROTECTION  
COMMISSION OF HILLSBOROUGH COUNTY

  
Janet L. Dougherty  
Executive Director

*Environmental Excellence in a Changing World*

**Roger P. Stewart Center**

**3629 Queen Palm Drive, Tampa, FL 33619 - (813) 627-2600 - [www.epchc.org](http://www.epchc.org)**

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**CERTIFICATE OF SERVICE**

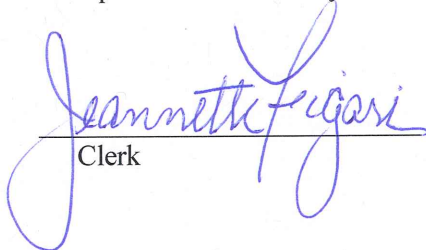
The undersigned duly designated deputy agency clerk hereby certifies that this Federally Enforceable State Operation Permit package was sent by electronic mail, or a link to these documents made available electronically on a publicly accessible server, with received receipt requested before the close of business on the date indicated below to the following persons.

David Dufort – Bausch & Lomb, Inc. [David.Dufort@bausch.com](mailto:David.Dufort@bausch.com)

Jeffery Rogers - Bausch & Lomb, Inc. [Jeffery.Rogers@bausch.com](mailto:Jeffery.Rogers@bausch.com)

Mitchell Hait, Ph.D., P.E. [haitinc@gmail.com](mailto:haitinc@gmail.com)

**FILING AND ACKNOWLEDGMENT FILED**, on this date, pursuant to Section 120.52(7), Florida Statutes, with the designated agency clerk, receipt of which is hereby acknowledged.

 2/19/2018  
Clerk Date

## SECTION 1. GENERAL INFORMATION

### PROPOSED PROJECT

This permit authorizes the operation of a pharmaceutical formulating and packaging facility. The process involves bottling products in an aseptic area. The process also involves the use of solvents and disinfectants to manually clean and sterilize the formulating and packaging equipment.

In the aseptic bottling area, filtered air is used to create a positive pressure, which helps prevent contaminants from entering the aseptic area and facilitates the discharge of solvent evaporative emissions during cleaning. The volatile organic compound (VOC) and Hazardous Air Pollutant (HAP), as applicable, emissions from the cleaning and sterilization operations are assumed to be emitted at 100% of the solvent usage, due to evaporation. Storage and handling of the solvent is controlled by the use of work practices to minimize evaporative losses.

Bausch & Lomb, Inc. also operates two identical, 14.6 MMBtu/hr., Cleaver Brooks boilers, Model No. CB-750-350. The boilers are used to provide steam for the hot water loop and for the formulating and packaging operation for improved cleaning and sterilization of the equipment. The boilers operate on natural gas with no backup fuel. The boilers are exempt from permitting pursuant to Rule 62-210.300(3)(a)34, F.A.C. Also onsite is a laboratory that is used for chemical or physical analyses. The laboratory is categorically exempt from permitting per Rule 62-210.300(3)(a)(12.), F.A.C.

The facility also operates the following three, diesel fuel fired emergency engines. The engines are categorically exempt from permitting pursuant to Rule 62-210.300(3)(a)(35), F.A.C., provided that all of the emergency engines at the facility burn less than 64,000 gallons of diesel fuel per twelve month period.

- Caterpillar, Model No. 3208, SN 90N72050, fire pump. This engine was rebuilt in 2015 and is subject to 40 CFR 60 Subpart IIII.
- Caterpillar, Model No. 3508/SR4, SN 1ZF00612, emergency engine. This engine is subject to 40 CFR 63 Subpart ZZZZ.
- Caterpillar, Model No. C27, SN CAT00C27HDWB02392. This engine was manufactured in 2013 and is subject to 40 CFR 60 Subpart IIII.

The existing facility consists of the following emissions units (EU):

EU No.	Description
001	Pharmaceutical Preparation

### APPLICABLE REGULATIONS

A summary of applicable regulations is shown in the following table.

Regulation	EU No.
<i>State Rule Citations</i>	
Rule 62-296.320, F.A.C. - General Pollutant Emission Limiting Standards	001
<i>Local Rule Citations</i>	
Rules of the EPCHC, Chapter 1-3 - Stationary Air Pollution and Ambient Air Quality Standards	001

## **SECTION 1. GENERAL INFORMATION**

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### **FACILITY REGULATORY CLASSIFICATION**

- The facility is not a major source of hazardous air pollutants (HAP).
- The facility does not operate units subject to the acid rain provisions of the Clean Air Act (CAA).
- The facility is not a Title V major source of air pollution in accordance with Chapter 62-213, F.A.C.
- The facility is not a major stationary source in accordance with Rule 62-212.400(PSD), F.A.C.

## SECTION 2. ADMINISTRATIVE REQUIREMENTS

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1. Permitting Authority: The permitting authority for this project is the Environmental Protection Commission of Hillsborough County. The mailing address is 3629 Queen Palm Dr., Tampa, Florida 33619. All documents related to applications for permits to operate an emissions unit shall be submitted to the Environmental Protection Commission of Hillsborough County.
2. Compliance Authority: All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the Environmental Protection Commission of Hillsborough County at: 3629 Queen Palm Dr., Tampa, Florida 33619.
3. Appendices: The following Appendices are attached as a part of this permit: Appendix A (Citation Formats and Glossary of Common Terms); Appendix B (General Conditions); Appendix C (Common Conditions); and Appendix D (Common Testing Requirements).
4. Applicable Regulations, Forms and Application Procedures: Unless otherwise specified in this permit, the construction and operation of the subject emissions units shall be in accordance with the capacities and specifications stated in the application. The facility is subject to all applicable provisions of: Chapter 403, F.S.; and Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, F.A.C. Issuance of this permit does not relieve the permittee from compliance with any applicable federal, state, or local permitting or regulations.
5. New or Additional Conditions: For good cause shown and after notice and an administrative hearing, if requested, the EPCHC may require the permittee to conform to new or additional conditions. The EPCHC shall allow the permittee a reasonable time to conform to the new or additional conditions, and on application of the permittee, the EPCHC may grant additional time. [Rule 62-4.080, F.A.C.]
6. Modifications: No new emissions unit shall be constructed and no existing emissions unit shall be modified without obtaining an air construction permit from the Department. Such permit shall be obtained prior to beginning construction or modification. [Rules 62-210.300(1) and 62-212.300(1)(a), F.A.C.]
7. Renewal: Prior to 60 days before the expiration date of this permit, the permittee shall apply for a renewal of the permit. A renewal application shall be timely and sufficient. If the application is submitted prior to 60 days before expiration of the permit, it will be considered timely and sufficient. If the renewal application is submitted at a later date, it will not be considered timely and sufficient unless it is submitted and made complete prior to the expiration of the operation permit. When the application for renewal is timely and sufficient, the existing permit shall remain in effect until the renewal application has been finally acted upon by the Department. [Rule 62-4.090, F.A.C.]
8. Annual Operating Report (AOR): The information required by the Annual Operating Report for Air Pollutant Emitting Facility (DEP Form No. 62-210.900(5)) shall be submitted by April 1 of each year, for the previous calendar year, to the Environmental Protection Commission of Hillsborough County. All synthetic non-Title V sources shall submit a completed DEP Form 62-210.900(5) unless the annual operating report is submitted using the DEP's electronic annual operating report software. Emissions shall be computed in accordance with the provisions of subsection 62-210.370(2), F.A.C. [Rule 62-210.370(3), F.A.C.]

*{Permitting Note: Resources to help you complete your AOR are available on the electronic AOR (EAOR) website at: <http://www.dep.state.fl.us/air/emission/eaor>. If you have questions or need assistance after reviewing the information posted on the EAOR website, please contact the Department by phone at (850) 717-9000 or email at [eaor@dep.state.fl.us](mailto:eaor@dep.state.fl.us).}*

## SECTION 2. ADMINISTRATIVE REQUIREMENTS

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9. The permittee shall not store, handle, process, or use in any process the volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems as follows and as deemed necessary and ordered by the Environmental Protection Commission of Hillsborough County: [Rule 62-296.320(1), F.A.C.]
  - A) Maintain tightly fitting cover, lids, etc. on all containers when they are not being handled, tapped, etc.
  - B) Where possible and practical, procure/fabricate a tightly fitting cover for any open trough, basin, etc. of VOC so that it can be covered when not in use.
  - C) Immediately attend to all spills/waste as appropriate
10. All applicable rules of the Environmental Protection Commission of Hillsborough County including design discharge limitations specified in the application shall be adhered to. The permit holder may also need to comply with county, municipal, federal, or other state regulations prior to construction. [Rule 62-4.070(7), F.A.C.]
11. When the Environmental Protection Commission of Hillsborough County (EPC) after investigation, has good reason (such as complaints, increased visible emissions or questionable maintenance of control equipment) to believe that any applicable emission standard contained in Rules 62-204, 62-210, 62-212, 62-296, or 62-297, F.A.C., or in a permit issued pursuant to those rules is being violated, it may require the owner or operator of the source to conduct compliance tests which identify the nature and quantity of pollutant emissions from the source and to provide a report on the results of said tests to the EPC. [Rule 62-297.310(8)(c), F.A.C.]
12. The permittee shall not cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor. [Rule 62-296.320(2), F.A.C.]
13. If the permittee wishes to transfer this permit to another owner, an "Application for Transfer of Air Permit" (DEP Form 62-210.900(7)) shall be submitted, in duplicate, to the Environmental Protection Commission of Hillsborough County within 30 days after the sale or legal transfer of the permitted facility. [Rule 62-4.120, F.A.C.]



### SECTION 3. EMISSIONS UNIT SPECIFIC CONDITIONS

#### A. EU No. 001 – Pharmaceutical Preparation

This section of the permit addresses the following emissions units.

EU No.	Description
001	Pharmaceutical Preparation

#### PERFORMANCE RESTRICTIONS

**A.1.** Permitted Capacity: As requested by the permittee, in order to limit the potential to emit for VOC and Hazardous Air Pollutants (HAP) emissions, the following limitations shall apply: [Rule 62-4.070(3), F.A.C. and Application No. 0570459-013-AF]

- A) The VOC emissions shall not exceed 45 tons per any 12 consecutive month period.
- B) The HAP, as defined in Rule 62-210.200, F.A.C., emissions shall be less than 10 tons in any 12 consecutive month period for any individual HAP, and less than 25 tons in any 12 consecutive month period for any combination of HAPs.

**A.2.** Hours of Operation: The hours of operation are not restricted. [Rule 62-4.070(3), F.A.C.]

#### RECORDS AND REPORTS

**A.3.** In order to comply with Specific Condition No. A.1, the permittee shall maintain monthly records of operations for the most recent three year period. The records shall be made available to the Environmental Protection Commission of Hillsborough County, state, or federal air pollution agency upon request. The records shall include, but not limited to, the following: [Rule 62-4.070(3) and 62-4.160(14), F.A.C.]

- A) Date
- B) The name and amount of material used
- C) Individual and total HAP content of each material (if applicable)
- D) VOC content, as applied, for each material
- E) Monthly total of material used
- F) Monthly total of material recycled or collected and disposed offsite (optional)
- G) Monthly total of individual HAP and total HAP emissions (if applicable)
- H) Monthly total VOC emissions
- I) Rolling twelve month total of material usages
- J) Rolling twelve month total of individual and total HAP emissions (if applicable)
- K) Rolling twelve month total of VOC emissions
- L) Safety data sheets (SDS) or other certified manufacturer provided information in order to verify the VOC and HAP content, as applicable, of each material

