Environmental Protection and Growth Management Department
POLLUTION PREVENTION DIVISION – AIR QUALITY PROGRAM
One North University Drive, Suite 203, Plantation, Florida 33324
954-519-1260 • FAX 954-519-1495

NOTICE OF AIR POLLUTION PERMIT

ISSUED TO:

PERMITTEE:
Actavis Laboratories FL, Inc.
Authorized Representative:
Mr. James Schwier, General Manager
Actavis Laboratories FL, Inc.
4955 Orange Drive
Fort Lauderdale, Florida 33314

AIRS ID NO: 0112197
Permit Number: 0112197-017-AC
Issue Date: June 16, 2015
Expiration Date: April 6, 2016

Facility Name: Actavis Laboratories FL, Inc.

Location: 4955 Orange Drive, and 4011 S.W. 47th Avenue, Fort Lauderdale, Broward County, Florida.

Project Description: Application for a construction permit to install a Glatt 30 fluid bed processor for use in the R & D Operations at 4955 Orange Drive, Fort Lauderdale, Florida. In addition, the existing emission units 005, 006 and 007, operating under permit 0112197-015-AF, will be included in this permit in order to keep all emissions units consolidated in one facility-wide permit; and to facilitate compliance verification. The addition of the Glatt 30 fluid bed processor will not result in a significant increase in potential emissions. Therefore, the facility will maintain its synthetic minor source status.

The Standard Industrial Classification (SIC) is 2834; and the North American Industrial Classification Standard (NAICS) Code is 355412. **Lat/Long:** 26°04'18" N / 80°12'40" W **UTM:** Zone 17; 578.2 km East; 2883.6 km North.

Statement of Basis: This permit is issued under the provisions of Chapter 403, Florida Statutes (F.S.) Florida Administrative Code (F.A.C.) Rules 62-4 and 62-210 through 62-297 (permitting requirements) and Broward County Code, Chapter 27 (protection of air quality) and in conformance with all existing regulations of the Florida Department of Environmental Protection (FDEP). The above named Permittee is hereby authorized to perform the work or operate the facility shown on the application and approved drawing(s), plans, and other documents attached hereto or on file with the Broward County Pollution Prevention Division (PPD) and made a part hereof.

This permit is organized by the following sections.

1. Facility Description
2. General Conditions
3. Facility-wide Conditions
4. Emissions Unit Specific Conditions, Sections [A] to [B]
5. Attachment A – Equipment List
6. Attachment B – Best Operational Practices Plan

Executed in Broward County, Florida

Robert C. Wong
2015.06.16 14:25:13 -04'00'

Robert C. Wong
Environmental Licensing Manager
Pollution Prevention Division

1. FACILITY DESCRIPTION

Actavis operates a pharmaceutical research and development (R & D) and manufacturing facility at two locations, 4955 Orange Drive, and 4011 S.W. 47th Avenue, Fort Lauderdale, Florida. The operation consists of three existing emissions units, which will include the manufacturing operation using a catalytic oxidizer, fluidized bed processors and coating pans, storage tanks, drying ovens, cleaning, miscellaneous R & D activities, tablet machine presses, central vacuum systems, and miscellaneous equipment and work areas.

The new system, which will be installed at 4955 Orange Drive location, will include the Glatt 30 fluid bed dryer, desiccant wheel, air handling unit (AHU), dust collector and controls. The dryer will use organic solvents and will be vented to a new dust collector for particulate matter control, followed by existing catalytic oxidizer #2 (ID-M461) for volatile organic compounds (VOC) control. The charging process will take place by means of a closed pneumatic transfer system which will move the raw materials into the dryer bowl. The bowl size will vary from 59 to 151 liters, depending on the product being evaluated. The raw materials will be mixed vigorously in the conditioned gas stream. The product will be dried to the desired end moisture content by the existing supply and by 1,770 cfm of air flow through the system.

When solution is required, a portable weigh scale, solution tank and pump will be positioned in the designated location within the R & D room. The tank weight will be constantly monitored by the weight scale. The product will be transferred from the solution tank by means of the portable pump to the dryer's spray system. The tank venting system will feature a nitrogen blanket maintained with a relief valve. The dryer will be cleaned with isopropyl alcohol. Evaporative losses from cleaning will not be controlled by the catalytic oxidizer. The washings will be collected and disposed of offsite at a licensed facility.

The air handling system is a once-through system with the inlet air being drawn from outdoors and ducted into the AHU, where it will be desiccated before being introduced to the fluid bed dryer. The fluidizing air will be exhausted from the dryer through a high-static pressure fan, and routed to the new dust collector and then to the catalytic oxidizer which will operate based upon the solvent or non-solvent load of the exhaust air. The processing room will be maintained under negative pressure relative to the surrounding space.

The maximum solution spray rate is 1,500 grams per minute; the average spray rate is 250 grams per minute. Approximately 146 batches will be produced per year; batch times range 4 to 18 hours, averaging 12 hours. Solvent usage is about 59.8 gallons per batch.

This pharmaceutical operations for Actavis Laboratories FL, Inc. located at 4955 Orange Drive, and 4011 SW 47th Avenue, Fort Lauderdale, Florida are classified as a synthetic minor source for VOC under the federal Prevention of Significant Deterioration (PSD) regulations and the Title V program by relying on control devices (i.e. catalytic oxidizers) to limit the VOC emissions to below 100 TPY. Any future permitting action that requires increasing the VOC limit to above 100 TPY would subject the source to an after-the-fact pre-construction review in accordance with Rule 62-212.400(2) (g), F.A.C. The source is also a synthetic minor source for HAPs under the Title III Hazardous Air Pollution Program. The 2.5 MMBTU/hr. Fulton Model VMP 60 natural gas-fired boiler, with a consumption rate of 2,392 cubic feet per hour; and with a heat content of 1,040 BTUC/cubic foot qualifies for permit exemption pursuant to Rule 62-210.300(3)(a)33, F.A.C. Also, there are no NSPS or NESHAPS that would apply to natural gas-fired boilers with heat input less than 10 MMBTU/hr. The addition of the Glatt 30 fluid bed processor dryer does not trigger additional requirements.

The operation is subject to the following State of Florida and Broward County rules:

F.A.C. 62.4.070(3)	Reasonable Assurance
F.A.C. 62-296.320(2)	Objectionable Odor Rule
F.A.C. 62-296.320(4) (b)	General Visible Emissions Standards -20% opacity facility-wide, per DEP Guidance ,DARM-PER- 33
F.A.C. 62-296.320(1) (a)	VOC or Organic Solvent Emissions
F.A.C. 62-297.310(7(b)	Recordkeeping
F.A.C. 62-210.370(3)	Reporting
Broward County Chapter 27	Air Pollution Control, Article IV, Sec. 27-175(b) & (c)

The facility consists of the following emission units:

E.U. ID No.	Brief Description
005	*Manufacturing Operations using Catalytic Oxidizers* – Volatile Organic Compound (VOC) and Hazardous Air Pollutant (HAP) emissions from fluid bed processors and coating pans are directed to dust collectors and catalytic oxidizers controls prior to discharge to the atmosphere. A Glatt 30 Fluid bed dryer for use in the R & D operations which includes the fluid bed dryer, desiccant wheel, air handling unit (AHU)), dust collector, and controls. See Attachment A – Equipment List.
006	*Fugitive Sources of VOC and HAP Emissions* - storage tanks, drying ovens, cleaning, miscellaneous research and development (R&D) activities, etc. See Attachment A – Equipment List.
007	*Fugitive Sources of Particulate Matter (PM/PM10) Emissions* - Manufacturing and R&D fluid-beds, drying ovens, tablet machines/presses, central vacuum systems, and miscellaneous equipment and work areas. See Attachment A – Equipment List.

Volatile organic compounds and HAP(s) emissions generated during the manufacturing of pharmaceutical products are collected in exhaust systems and directed to a vapor collection and processing system (VCPS). The VCPS includes all equipment such as ducts, valves, exhaust system, computer hardware, software, and catalytic oxidizers that manages the VOC and HAP emissions from the time of generation until the final discharge to the atmosphere.

2. GENERAL CONDITIONS

1. Terms of Permit. The terms, conditions, requirements, limitations and restrictions set forth in this permit, are "permit conditions" and are binding and enforceable pursuant to Sections 403.141, 403.727, or 403.859 through 403.861, F.S. The Permittee is placed on notice that the PPD will review this permit periodically and may initiate enforcement action for any violation of these conditions.
   [Rule 62-4.160 (1), F.A.C.]

2. Permit Validity. This permit is valid only for the specific processes and operations applied for and indicated in the approved drawings or exhibits. Any unauthorized deviation from the approved drawings, exhibits, specifications, or conditions of this permit may constitute grounds for revocation and enforcement action by the PPD.
   [Rule 62-4.160 (2), F.A.C.]

3. Disclaimer. As provided in subsections 403.087(6) and 403.722(5), F.S., the issuance of this permit does not convey any vested rights or exclusive privileges. Neither does it authorize any injury to public or private property or any invasion of personal rights, or any violations of federal, state or local laws or regulations. This permit is not a waiver of or approval of any other permit that may be required for other aspects of the total project which are not addressed in this permit.
   [Rule 62-4.160 (3), F.A.C.]

4. Disclaimer. This permit conveys no title to land or water, does not constitute State recognition or acknowledgment of title, and does not constitute authority for the use of submerged lands unless herein provided and the necessary title or leasehold interest have been obtained from the State. Only the Trustees of the Internal Improvement Trust Fund may express State opinion as to title.
   [Rule 62-4.160 (4), F.A.C.]

5. Liability. This permit does not relieve the Permittee from liability for harm or injury to human health or welfare, animal, or plant life, or property caused by the construction or operation of this permitted source, or from penalties therefore; nor does it allow the Permittee to cause pollution in contravention of Florida Statutes and FDEP rule, unless specifically authorized by an order from the PPD.
   [Rule 62-4.160 (5), F.A.C.]

6. Operation and Maintenance. The Permittee shall properly operate and maintain the facility and systems of treatment and control (and related appurtenances) that are installed and used by the Permittee to achieve compliance with the conditions of this permit, as required by county and state rules. This provision included the operation of backup or auxiliary facilities or similar systems when necessary to achieve compliance with the conditions of the permit and when required by PPD and FDEP rules.
   [Rule 62-4.160 (6), F.A.C.]

7. Onsite Inspection Activities. The Permittee, by accepting this permit, specifically agrees to allow authorized PPD personnel, upon presentation of credentials or other documents as may be required by law and at reasonable times (depending on the nature of the concern being investigated), access to the premises where the permitted activity is located or conducted to:
   (a) Have access to and copy any records that must be kept under conditions of the permit;
   (b) Inspect the facility, equipment, practices, or operations regulated or required under this permit; and
   (c) Sample or monitor any substances or parameters at any location reasonably necessary to assure compliance with this permit or PPD and FDEP rules.
   [Rule 62-4.160 (7), F.A.C.]

8. Notice of Noncompliance. If, for any reason, the Permittee does not comply with or will be unable to comply with any condition or limitation specified in this permit, the Permittee shall immediately provide PPD with the following information:
   (a) A description of and cause of noncompliance; and
   (b) The period of noncompliance, including dates and times, or, if not corrected, the anticipated time the noncompliance is expected to continue, and steps being taken to reduce, eliminate, and prevent recurrence of the noncompliance. The Permittee shall be responsible for any enforcement action by PPD for penalties or for revocation of this permit.
   [Rule 62-4.160 (8), F.A.C.]

9. Reporting Noncompliance. The Permittee shall report any periods of noncompliance to the PPD immediately by phone at 954-519-1499 or by Email at PPDHOTLINE@broward.org. This also applies when the period of non-compliance is first determined after normal business hours or on weekends and holidays.
   [Rules 62-4.130 and 62-4.070(3), F.A.C.]

10. Evidence Materials. By accepting this permit, the Permittee understands and agrees that all records, notes, monitoring data and other information relating to the construction or operation of this permitted facility or activity, that are submitted to the PPD, may be used by the PPD as evidence in any enforcement proceeding arising under the Florida Statues or F.A.C. rules, except where such use is prohibited by Section 403.111 and 403.73, Florida Statutes. Such evidence shall only be used to the extent it is consistent with the Florida Rules of Civil Procedure and appropriate evidentiary rules.
    [Rule 62-4.160 (9), F.A.C.]

11. Rule Changes. The Permittee agrees to comply with changes in Florida Department of Environmental Protection rules and Florida Statutes after a reasonable time for compliance; provided, however, the Permittee does not waive any other rights granted by Florida Statutes or FDEP rules.
    [Rule 62-4.160 (10), F.A.C.]

12. Permit Transfer. This permit is transferable only upon PPD approval in accordance with Rule 62-4.120 and 62-730.300 F.A.C., as applicable. The Permittee shall be liable for any non-compliance of the permitted activity until the transfer approved by the PPD.
    [Rule 62-4.160 (11), F.A.C.]

13. Work Site Copy. This permit or a copy thereof shall be kept at the work site of the permitted activity.
    [Rule 62-4.160 (12), F.A.C.]

14. Miscellaneous Compliance Requirements. The Permittee shall comply with the following:

(a) Upon request, the Permittee shall furnish all records and plans required under FDEP rules. During enforcement actions, the retention period for all records will be extended automatically unless otherwise stipulated by the PPD.

(b) The Permittee shall hold at the facility or other location designated by this permit records of all monitoring information (including all calibration and maintenance records and all original strip chart recording for continuous monitoring instrumentation) required by the permit, copies of all reports required by this permit, and records of all data used to complete the application for this permit. These materials shall be retained at least three years from the date of the sample, measurement, report, or application unless otherwise specified by PPD rule.

(c) Records of monitoring information shall include:

1. The date, exact place, and time of sampling or measurements;
2. The person responsible for performing the sampling or measurements;
3. The date's analyses were performed.
4. The person responsible for performing the analyses;
5. The analytical techniques or methods used;
6. The results of such analyses.

[Rule 62-4.160 (14), F.A.C.]

15. Information Submittal. When requested by the PPD, the Permittee shall within a reasonable time furnish any information required by law which is needed to determine compliance with the permit. If the Permittee becomes aware the relevant facts were not submitted or were incorrect in the permit application or in any report to the PPD, such facts or information shall be corrected promptly.
[Rule 62-4.160 (15), F.A.C.]

16. Rules Adoption. Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, as amended, are adopted by Broward County Code, Sec. 27-173.
[Broward County Code, Sec. 27-173]

3. FACILITY-WIDE CONDITIONS

17. Objectionable Odor. No person shall 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. and Broward County Code, Sec. 27-175(e)]

18. VOC or Organic Solvents Emissions. The owner or operator shall allow no person to store, pump, handle, process, load, unload or use in any process or installation, volatile organic compounds or organic solvents without applying known and existing vapor emission control devices or systems deemed necessary and ordered by the PPD.

The following requirements are deemed necessary by the PPD: use of a VCPS (defined below) to control VOCs.
[Rule 62-296.320(1), F.A.C., Rule 62-4.070(3), F.A.C., and Broward County Code, Sec. 27-175(f)]

{**VCPS Definition:** The vapor collection and processing system (VCPS) includes all equipment such as ducts, valves, exhaust system, computer hardware and software, and catalytic oxidizers that manages the VOC and HAP emissions from the time of generation until the final discharge to the atmosphere.}

19. General Visible Emissions. No person shall cause, let, permit, suffer or allow to be discharged into the outdoor atmosphere any air pollutants from sources, the opacity of which is equal or greater than 20 percent. EPA Method 9 is the method of compliance pursuant to Chapter 62-297, F.A.C. This regulation does not impose a specific testing requirement.
[Rule 62-296.320(4) (b) (1), F.A.C., DEP Guidance, DARM-PER-33]

20. Unconfined emissions of particulate matter. No person shall cause, let, permit, suffer or allow emission of particulate matter from any source whatsoever, including but not limited to vehicular movement, transportation of materials, construction, alteration, demolition or wrecking, or industrial-related activities

such as loading, unloading, storing or handling without taking reasonable precautions to prevent such emissions.
Reasonable precautions may include, but shall not be limited to, the following:
a) Use of hoods, fans, filters and similar equipment to contain, capture and/or vent particulate matter.
[Rule 62-296.320(4) (c) F.A.C. and Broward County Code Sec. 27-177(b)]

21. Concealment. No person shall build, erect, install, or use any article, machine, equipment or other contrivance, the use of which will conceal any emission which would otherwise constitute a violation of any provisions of Broward County Codes.
[Broward County Code, Sec. 27-175(b)]

22. Circumvention. No person shall circumvent any air pollution device, or allow the emission of air pollutants without the applicable air pollution control device operating properly.
[Rule 62-210.650 F.A.C and Broward County Code, Sec. 27-175(c)]

23. Maintenance. No person shall operate any air pollution control equipment or systems without proper and sufficient maintenance to assure compliance with Broward County Codes.

In addition, the owner or operator shall implement the following Preventive Maintenance Inspection Program (PMIP) by:
(1) Conducting and documenting ongoing training for current and new employees on the verification of the operability of each VCPS;
(2) Inspecting each VCPS at least once a month and document results at least 5 days after each inspection;
(3) Obtaining a certified verification check from the manufacturer on operability for all VCPS at least once a year and after each modification or repair of a VCPS;
(4) Conducting VOC destruction efficiency testing on each catalytic oxidizer (see "*Testing*", below)
[Rule 62-4.070(3), F.A.C. and Broward County Code, Sec. 27-175(d)]

(*Permitting Note*: PPD considers an oxidizer efficiency equal to or greater than 95 percent (used for calculations in the permit application) with no leaks in the vapor collection system to be an indicator of acceptable operation and maintenance of the VCPS. Operating at efficiencies below 95 percent could be considered (on a case-by-case basis) to be a violation of the PMIP.)

24. Special Compliance Tests. When PPD 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 a PPD rule or in a permit issued pursuant to those rules is being violated, it shall require the owner or operator of the emissions units to conduct compliance tests which identify the nature and quantity of pollutants emissions from the emissions unit and to provide a report on the results of said tests to the PPD.
[Rule 62-297.310(7) (b), F.A.C.]

25. Operating Permit. Sixty days before the expiration date of this construction permit, the permittee shall apply for an operation permit using the forms incorporated by reference in the specific rule chapter for this type of permit.
[Rule 62-4.090 F.A.C.]
{Permitting Note: The permittee may also elect to submit the application electronically using the Electronic Permit Submittal and Processing system (EPSAP) via the http://www.dep.state.fl.us/air/emission/epsap/default.htm website, along with the processing fee established in Rule 62-4.050(4), F.A.C. , [62-4.090(1) and 62-4.050(4), F.A.C.]

26. Annual Operation Report (AOR). The AOR shall be submitted to the PPD by April 1 of the following year. If the permittee elects to use FDEP's electronic annual operation report software (EAOR), the report must be submitted directly to FDEP and there is no requirement to submit a copy to PPD.
[Rule 62-210.370(3), F.A.C.]
{Permitting Note. Information on the EAOR submittal is available at http://www.dep.state.fl.us/air/emission/eaor/default.htm}

4. EMISSIONS UNIT SPECIFIC CONDITIONS

Subsection A. This section addresses the following emissions unit.

E.U. ID No.	Brief Description
005	*Manufacturing Operations using Catalytic Oxidizers* – Volatile Organic Compound (VOC) and Hazardous Air Pollutant (HAP) emissions from fluid bed processors and coating pans are directed to dust collectors and catalytic oxidizers controls prior to discharge to the atmosphere. A Glatt 30 Fluid bed dryer for use in the R & D operations which includes the fluid bed dryer, desiccant wheel, air handling unit (AHU)), dust collector, and controls. See Attachment A – Equipment List
006	*Fugitive Sources of VOC and HAP Emissions* - storage tanks, drying ovens, cleaning, miscellaneous research and development (R&D) activities, etc. See Attachment A – Equipment List
007	*Fugitive Sources of Particulate Matter (PM/PM10) Emissions* - Manufacturing and R&D fluid-beds, drying ovens, tablet machines/presses, central vacuum systems, and miscellaneous equipment and work areas. See Attachment A – Equipment List

Volatile organic compounds and HAP(s) emissions generated during the manufacturing of pharmaceutical products are collected in exhaust systems and directed to a vapor collection and processing system (VCPS). The VCPS includes all equipment such as ducts, valves, exhaust system, computer hardware, software, and catalytic oxidizers that manages the VOC and HAP emissions from the time of generation until the final discharge to the atmosphere.

Emission Limiting Standards

A.1. Synthetic Minor Source of VOC and HAP Emissions. In order to maintain a synthetic minor classification under the PSD~~, Title V,~~ and Title III permitting program, the owner or operator shall ensure that in any consecutive fifty-two (52) week period, the emissions from all sources, including fugitive emissions, within the combined facilities (i.e. 4011 & 4955) remain below the following threshold: 100 tons of VOC, 10 tons of any individual HAP, and 25 tons of total HAPs. Any future modification that requires increasing the VOC emissions limit to a level greater than 100 TPY would subject the facility to pre-construction review under the PSD permitting program.
[Rule 62-4.070(3)&(5), F.A.C., Rule 62-210.200(194)(a)&(b), F.A.C., Rule 62-212.400, F.A.C. and Rule 62-212.500, F.A.C.]

A.2. Non-fugitive VOC Emissions from Sources using the VPCS (see note below).

(1) The efficiency of the catalytic oxidizers shall be 95 percent or higher.
(2) The amount of VOC solvents used in batch operations with exhaust emissions directed to the VPCS shall not exceed 1,800 tons during any rolling 52 week period.
(3) The collection efficiency of the VPCS shall be 100 percent (i.e. no leaks).
[Rule 62-4.070(3) & (5), F.A.C.]

(*Permitting Note*. The 1,800 tons limit corresponds to 90 TPY non-fugitives emissions from the oxidizers (assuming 95 percent oxidizer efficiency). Exceedance of 90 TPY requires a permit revision to increase the frequency of record-keeping and facility-wide emissions calculations in order provide PPD with additional reasonable assurance of synthetic minor status.)

Method of Operation

A.3. Modes of Operation. The modes of operation are Non-Solvent (aqueous) and Solvent (VOC). The VPCS shall be in the "Solvent" mode for batch processing so that VOC emissions generated during solvent spraying operations are directed to the oxidizer for processing (instead of directly to the atmosphere).
[Rule 62-4.070(3) & (5), F.A.C.]

(*Permitting Note*. Mechanical or computer logic failure could cause the system to go into the oxidizer bypass mode (i.e. Non-Solvent mode) instead of Solvent mode during operations that generates VOC emissions.)

A.4. Operation during VCPS failure.

(1) *VCPS failure due to malfunction.* Excess emissions resulting from startup, shutdown or malfunction of any emissions unit shall be permitted providing:

(a) The best operational practices plan (BOPP) to minimize emissions is adhered to; and

(b) The duration of excess emissions shall be minimized but in no case exceed two hours in any 24 hour period unless specifically authorized by the PPD for longer duration.

(2) – (3) [Reserved]

(4) *VCPS failure not due to malfunction.* Excess emissions which are caused entirely or in part by poor maintenance, poor operation, or any other equipment or process failure which may reasonably be prevented during startup, shutdown, or malfunction shall be prohibited.

[Rules 62-210.700(1) and (4), F.A.C.]

(*Permitting Note*. Malfunction means any unavoidable mechanical and/or electrical failure of the VCPS or process equipment or of a process resulting in operation in an abnormal or unusual manner. Failures caused in part by poor maintenance or careless operations are not malfunctions. The owner or operator could use historical VCPS failure reports to demonstrate that the cause of failure was abnormal or unusual.)

(*Permitting Note*. See Attachment B for BOPP)

Compliance Testing Requirements

A.5. Annual Emissions Tests Required. The owner or operator shall conduct emissions testing annually on each VCPS to determine the collection system efficiency and the VOC destruction efficiency for each catalytic oxidizer from all facility operations. All repairs to the VCPS (including oxidizer functionality testing) shall be conducted prior to formal testing.
[Rule 62-4.070(3) & (5) F.A.C., Rule 62-297.310(8) (a) 2., F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]

A.6. Catalytic Oxidizer/VCPS tests shall be conducted in accordance with the appropriate USEPA Method(s) and Actavis's Catalytic Oxidizer – Test Protocol submitted to the PPD (dated April 25, 2005). Tests shall be conducted under facility and equipment representative performance and maximum worst case operating conditions that will result in the lowest expected VOC destruction efficiency from each catalytic oxidizer.
[Rule 62-4.070(3) & (5) F.A.C., Rule 62-297.310(3), F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]

A.7. EPA Test Method 25A (40 CFR 60, Appendix A) shall be used to demonstrate the destruction efficiency of each catalytic oxidizer operating at both Actavis facilities indicated in this permit.
[Rule 62-4.070(3) & (5) F.A.C., Rule 62-297.401(25), F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]

Notification Requirements

A.8. Testing Notification. The owner or operator shall notify the PPD, at least 15 days prior to the date on which each VCPS/Catalytic Oxidizer(s) test is to begin, of the date, time, and place of each such test, and the test contact person who will be responsible for coordinating and having such test conducted for the owner or

operator. The owner or operator shall also provide PPD with the test protocol at least 30 days prior to testing. [Rule 62-4.070(3) & (5) F.A.C. and Rule 62-297.310(7) (a) 9. F.A.C.]

A.9. Notification of VCPS Failure Due to Malfunction. In case of excess emissions resulting from malfunctions, the owner or operator shall immediately notify the PPD in accordance with Rule 62-4.130, F.A.C. which requires that the notification includes pertinent information as to the cause of the problem, and what steps are being taken to correct the problem and to prevent its recurrence.
[Rule 62-210.700(6) F.A.C., Rule 62-4.130 F.A.C. and Rule 62-4.070(3) & (5) F.A.C.]

(*Permitting Note*. Notification of VCPS and/or Catalytic Oxidizer failure not due to malfunction shall be in accordance with General Conditions No. 8 and 9.)

Recordkeeping Requirements

A.10. Emission Records. The owner or operator shall maintain records of: (1) weekly calculations of the VOC and HAP emissions (i.e. fugitives and non-fugitives) from all facility pharmaceutical manufacturing operations, and (2) calculations of the entire facility VOC and HAP emissions (in tons/year) for a rolling fifty-two (52) week period. The owner or operator shall use the VOC destruction efficiency obtained from the most recent VCPS performance testing to calculate non-fugitive emissions from the VCPS.
[Rule 62-4.070(3) & (5), F.A.C.]

A.11. Emissions Recordkeeping. The owner or operator shall demonstrate compliance with permit Specific Condition No. A.1 and A.2 by maintaining records of the facility's JDE Enterprise Tracking System and Master Batch Records (or any other equivalent tracking and monitoring system), indicating the amount of raw material solvents dispensed and the %VOC and %HAP content of pharmaceutical manufacturing operations on a weekly basis for a 52-week rolling period. The owner or operation shall retain a copy of JDE Enterprise Tracking System records and Master Batch Records to demonstrate and compute emissions in accordance with Specific Conditions No. A.12 and A.13 for a period of (5) five years from the date on which such emissions information is submitted to the Department for any regulatory purpose.
[Rule 62-210.370(2) (h) F.A.C. and Rule 62-4.070(3) & (5), F.A.C.]

A.12. Emissions Computation.

(a) The owner or operator shall employ, on a pollutant-specific basis, the most accurate methodology to compute the emissions of a pollutant from an emissions unit. An owner or operator may use materials used in or at the emissions unit(s); and

(b) Assumes that the emissions unit(s) emits all of the pollutant that is contained in or created by any material used in or at the emissions unit if it cannot otherwise be accounted for in the process or in the capture and destruction of the pollutant by the unit's air pollution control equipment.

Where the vendor of a raw material which is used in or at the emissions unit(s) publishes a range of pollutant content from such material, the owner or operator shall use the highest value of the range to compute the emissions, unless the owner or operator demonstrates using site-specific data that another content within the range is more accurate. In the case of an emissions unit using coatings or solvents, the owner or operator shall document, through purchase receipts, records and sales receipts, the beginning and ending VOC and HAP inventories, the amount of VOC and HAP purchased during the computational period, and the amount of VOC and HAP disposed of in the liquid phase during such period.
[Rule 62-210.370(2) (a) and (c), F.A.C. and Rule 62-4.070(3) & (5), F.A.C.]

A.13. Fugitive Emissions. In computing the emissions of a pollutant from a facility or emissions unit, the owner or operator shall account for the fugitive emissions of the pollutant, to the extent quantifiable, associated with such facility or emissions unit.
[Rule 62-210.370(2) (g), F.A.C. and Rule 62-4.070(3) & (5), F.A.C.]

A.14. VCPS Records. The owner or operator shall maintain all records related to each VCPS including, but not limited to, operator training, periodic inspections, failures, maintenance and testing, in a form suitable for

review by PPD for a period of 5 years. Records of verification check for operability shall be maintained for the life of the VCPS.
[Rules 62-4.070(3) & (5), F.A.C.]

Reporting Requirements

A.15. Emissions Reporting. The owner or operator shall retain a copy of all records used to compute emissions, including by not limited to, raw material solvent usage, JDE Enterprise Tracking System solvent and non-solvent dispensing/usage information, Master Batch Records, percent (%) VOC and percent (%)HAP quantities dispensed and emitted per manufacturing operations, and any other information relating to facility emissions and emissions calculations for a period of five (5) years. All records shall be made readily available to PPD personnel upon request.
[Rule 62-210.370(2(h), F.A.C., Rule 62-4.070(3) & (5), F.A.C.]

A.16. Test Reports. The owner or operator of an emissions unit for which a compliance test is required shall file a report with the PPD on the results of each such test. The required test report shall be filed to the PPD as soon as practical but no later than 45 days after the last sampling run of each test is completed. The test report shall provide sufficient detail on the emissions unit(s) tested and the test procedures used to allow the PPD to determine if the test was properly conducted and the test results properly computed. The report shall also contain results of supplementary system tests (e.g. the oxidizer's functionality reports to verify the operation modes (see "Modes of Operation" above)).

As a minimum, the test report shall provide the following information:

a. The type, location, and designation of the emissions unit tested.
b. The facility at which the emissions unit is located.
c. The owner or operator of the emissions unit.
d. The normal type and amount of fuels used and materials processed, and the types and amounts of fuels used and material processed during each test run.
e. The means, raw data and computations used to determine the amount of fuels used and materials processed, if necessary to determine compliance with an applicable emission limiting standard.
f. The type of air pollution control devices installed on the emissions unit, their general condition, their normal operating parameters and their operating parameters during each test run.
g. A sketch of the duct within 8 stack diameters upstream and 2 stack diameters downstream of the sampling ports, including the distance to any upstream and downstream bends or other flow disturbances.
h. The date, starting time and duration of each sampling run.
i. The test procedures used, including any alternative procedures authorized pursuant to Rule 62-297.620, F.A.C. Where optional procedures are authorized in this chapter, indicate which option was used.
j. The number of points sampled and configuration and location of the sampling plane.
k. For each sampling point for each run, the dry gas meter reading, velocity head, pressure drop across the stack, temperatures, average meter temperatures and sample time per point.
l. The type, manufacturer and configuration of the sampling equipment used.
m. Data related to the required calibration of the test equipment.
n. Data on the identification, processing and weights of all filters used.
o. Data on the types and amounts of any chemical solutions used.
p. Data on the amount of pollutant collected from each sampling probe, the filters, and the impingers, are reported separately for the compliance test.
q. The names of individuals who furnished the process variable data, conducted the test, analyzed the samples and prepared the report.
r. All measured and calculated data required to be determined by each applicable test procedure for each run.
s. The detailed calculations for one run that relate the collected data to the calculated emission rate.

t. The applicable emission standard, and the resulting maximum allowable emission rate for the emissions unit, plus the test result in the same form and unit of measure.

u. A certification that, to the knowledge of the owner or his authorized agent, all data submitted are true and correct. When a compliance test is conducted for the PPD or its agent, the person who conducts the test shall provide the certification with respect to the test procedures used. The owner or his authorized agent shall certify that all data required and provided to the person conducting the test are true and correct to his knowledge.

[Rule 62-4.070(3) & (5), F.A.C., Rule 62-297-310(10), F.A.C. and Settlement Agreement - Cases No. 02-0023 and 02-0024]

A.17. **VCPS** Failure Report. The owner or operator shall submit an incident report on each VCPS failure within fifteen (15) days of the event. The report shall include pertinent information as to the cause of the failure, steps taken to correct the problem and to prevent a reoccurrence, and an estimate of the excess VOC emissions due to the VCPS failure along with the total facility wide VOC emissions for the previous 52 weeks.
[Rule 62-4.070(3) & (5), F.A.C.]

Actavis Laboratories FL, Inc. – Florida
Revised Attachment A – Equipment List*

*This list represents permanent, fixed pieces of equipment only.

Unit Number	Description	Equipment Location	Equipment Added in the past 5 yrs.
P-001/1	FLUID BED/GLATT	4955	
P-105	FLUID BED/GLATT	4955	
P-106	FLUID BED/GLATT	4955	
P-107	FLUID BED/GLATT	4955	
P-108	FLUID BED/GLATT	4955	
P-1232	FLUID BED/GLATT	4955	X
P-385	FLUID BED/GLATT	4955	
P-386	FLUID BED/GLATT	4955	
P-387	FLUID BED/GLATT	4955	
P-667	FLUID BED/GLATT	4955	X
P-668	FLUID BED/GLATT	4955	X
F-164	FLUID BED/GLATT	4955	
F-165	FLUID BED/GLATT	4955	
GPCG-30	FLUID BED/GLATT	4955	
RD-003	FLUID BED/GLATT	Not Specified	
M-149	OXIDIZER #1	4955	
M-461	OXIDIZER #2	4955	
M-827	OXIDIZER #3	4955	X
P-1114	GRANULATOR/GRAL	4955	
P-280	GRANULATOR/GRAL	4955	X
P-2955	GRANULATOR/GRAL	Not Specified	X
P-607	GRANULATOR/GRAL	4955	
F-191	PAN COATER	4955	
P-1320	PAN COATER	4955	X
P-188	PAN COATER	Not Specified	
P-388	PAN COATER	4955	
P-389	PAN COATER	4955	
P-390	PAN COATER	4955	
P-391	PAN COATER	4955	
P-592	PAN COATER	4955	
P-672	PAN COATER	4955	X
P-673	PAN COATER	4955	X
9-890	PAN COATER	4955	X
P-981	PAN COATER	4955	X
P-982	PAN COATER	4955	X

P-983	PAN COATER	4955	X
P-984	PAN COATER	4955	
P-985	PAN COATER	4955	
P-993	PAN COATER	4955	
RD-016	PAN COATER	4011	
P-003/2	ENCAPSULATOR	Not Specified	
P-068	ENCAPSULATOR	Not Specified	
P-1522	ENCAPSULATOR	Not Specified	X
P-212	ENCAPSULATOR	Not Specified	
P-240	ENCAPSULATOR	Not Specified	X
P-963	ENCAPSULATOR	Not Specified	
RD-098	ENCAPSULATOR	Not Specified	X
F-207	DRYING OVEN	4955	
F-208	DRYING OVEN	4955	
F-219	DRYING OVEN	4955	
F-220	DRYING OVEN	4955	
P-004/3	DRYING OVEN	Not Specified	
P-004/5	DRYING OVEN	Not Specified	
P-1117	DRYING OVEN	4955	X
P-1118	DRYING OVEN	4955	X
P-1119	DRYING OVEN	4955	X
P-1321	DRYING OVEN	Not Specified	X
P-1322	DRYING OVEN	Not Specified	X
P-1323	DRYING OVEN	Not Specified	X
P-202	DRYING OVEN	Not Specified	
P-203	DRYING OVEN	Not Specified	
P-204	DRYING OVEN	Not Specified	
P-205	DRYING OVEN	Not Specified	
RD-043	DRYING OVEN	Not Specified	X
F-295	TABLET PRESS	Not Specified	X
F-352	TABLET PRESS	Not Specified	X
P-053	TABLET PRESS	Not Specified	
P-1092	TABLET PRESS	Not Specified	
P-1129	TABLET PRESS	Not Specified	
P-1253	TABLET PRESS	Not Specified	X
P-222	TABLET PRESS	Not Specified	
P-828	TABLET PRESS	Not Specified	
P-846	TABLET PRESS	Not Specified	X
RD-001	TABLET PRESS	Not Specified	X
RD-012	TABLET PRESS	Not Specified	X
RD-100	TABLET PRESS	Not Specified	X
RD-102	TABLET PRESS	Not Specified	X

RD-119	TABLET PRESS	Not Specified	X
WP0007	TABLET PRESS	Not Specified	
P-221	TABLET PRESS	Not Specified	
P-002/1	BLENDER	Not Specified	X
P-122	BLENDER	Not Specified	X
P-123	BLENDER	Not Specified	X
P-156	BLENDER	Not Specified	
P-189	BLENDER	Not Specified	X
P-338	BLENDER	Not Specified	
P-986	BLENDER	Not Specified	X
P-987	BLENDER	Not Specified	X
M-3714	CENTRAL VACUUM SYSTEM	Not Specified	
M-542	CENTRAL VACUUM SYSTEM	Not Specified	X
M-543	CENTRAL VACUUM SYSTEM	Not Specified	X
P-1227	CENTRAL VACUUM SYSTEM	Not Specified	
M-170	GENERATOR	Not Specified	
M-171	GENERATOR	Not Specified	
M-172	GENERATOR	Not Specified	
M-211	GENERATOR	Not Specified	
M-3552	GENERATOR	Not Specified	
M-296	PROCESS BOILER	Not Specified	
M-297	PROCESS BOILER	Not Specified	
M-987	PROCESS BOILER	Not Specified	

Equipment Permanently Removed
(Subsequent to issuance of Permit 0112197-013-AF)

Unit Number	Description
P-113	FLUID BED/GLATT
F-172	PAN COATER
P-226	TABLET PRESS
P-004/6	DRYING OVEN
P-055	BLENDER
M-107	CENTRAL VACUUM SYSTEM

Attachment B
Best Operational Practices Plan

PURPOSE:

The purpose of this Best Operational Practices Plan (BOPP) is to minimize emissions during a Vapor Collection & Processing System (oxidizer) malfunction or interruption.

PROCEDURES:

1. At the time of the oxidizer failure due to a malfunction, dampers for exhaust process air will be redirected to allow the exhaust to discharge directly to atmosphere.
   1.1. An alarm will be displayed on the HMI
   1.2. An alarm will be displayed on the Building Maintenance System
   1.3. Production personnel will contact the maintenance department
   1.4. Watson will immediately begin to rectify the oxidizer failure.

2. < 2 Hour - If it appears that the maintenance will have the malfunction diagnosed and repaired in less than 2 hours of the failure:
   2.1. Maintenance fix problem
   2.2. Once fixed, redirect dampers for exhaust to back through the oxidizer
   2.3. Production will fill out attached form and submit to EHS Manager within 24 hours

3. > 2 Hour - If it appears that the malfunction cannot be rectified within 2 hours, the following will occur:
   3.1. The maintenance mechanic diagnosing the situation will notify his supervisor.
      3.1.1. If the supervisor is unavailable, the maintenance mechanic shall continue to call the chain of command until someone is notified.
   3.2. Supervisor or above will notify:
   Broward County PPD at 954-519-1220, Monday – Friday 8:00 am – 4:00 pm.
   If unable to contact someone at this number or non-compliance is first determined after normal business hours or on weekends and holidays, the following number must be used954-519-1499.
      3.2.1. Notification shall also be made PPDHOTLINE@broward.org with a copy to the EHS Manager
      3.2.2. Information for notification must include:
         3.2.2.1. Name of facility
         3.2.2.2. Location of facility
         3.2.2.3. Air permit number 0112197-012-AO
         3.2.2.4. General condition – 15: <u>Reporting of Non-compliance, which states:</u> The Permittee shall report any periods of noncompliance to the PPD immediately.
         3.2.2.5. expected duration of non-compliance
   3.3. After the failure has been corrected and operation of the oxidizer has been restored, Actavis will redirect the exhaust stream back to the oxidizer.
   3.4. The attached form will be provided to the EHS Manager within 24 hours of the oxidizer failure/interruption

4. No new batch processing requiring solvent spraying shall be initiated if the oxidizer is not operational.

5. EHS manager will provide a written report to PPD within 14 days of malfunction/interruption as describing the event and corrective actions.

Oxidizer Failure
Alarm sent to BMS
Production to notify Maintenance
If diagnosis and repaired < 2 hours
If diagnosis and repair > 2 hours
If diagnosis and repair > 2 hours Maintenance Mechanic notify supervisor
Supervisor notify Broward County via telephone & email
Once repaired, redirect exhaust to oxidizer