March 22, 2013

CERTIFIED MAIL NO. 7006 0810 0000 7059 9093
RETURN RECEIPT REQUESTED

**PERMITTEE**

Noven Pharmaceuticals, Inc.
11960 SW 144 Street
Miami, FL 33186

*Authorized Representative:*
Mr. Richard Gilbert, Vice President Operations

Air Permit No. 0250616-013-AC
Permit Expires: March 21, 2014

Noven Pharmaceuticals, Inc.
Minor Source Air Construction Permit
Project: Replacement of Existing Thermal Oxidizer

This is the final air construction permit No. 0250616-013-AC, which authorizes the replacement of the existing East Coater thermal oxidizer with a recuperative thermal oxidizer (RCO). The proposed work will be conducted at Noven Pharmaceuticals, Inc. which engages in the manufacturing of transdermal patches. [Standard Industrial Classification (SIC) No. 2834; NAICS 325412]. The facility is located in Miami-Dade County at 11960 SW 144 Street & 14500 SW 119 Avenue, Miami, Florida 33186. The Lat./Long. coordinates are 25° 38' 2" N / 80° 23' 14" W.

This final permit is organized by the following sections.

Section 1. General Information

Section 2. Administrative Requirements

Section 3. Emissions Unit Specific Conditions

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.

This air pollution construction permit is issued under the provisions of: Chapter 403 of the Florida Statutes (F.S.) and Chapters 62-4, 62-204, 62-210, 62-212, 62-296 and 62-297 of the Florida Administrative Code (F.A.C.). The permittee is authorized to conduct the proposed work in accordance with the conditions of this permit. This project is subject to the general preconstruction review requirements in Rule 62-212.300, F.A.C. and is not subject to the preconstruction review requirements for major stationary sources in Rule 62-212.400, F.A.C. for the Prevention of Significant Deterioration (PSD) of Air Quality.

Upon issuance of this final permit, any party to this order has the right to seek judicial review of it under Section 120.68 of the Florida Statutes by filing a notice of appeal under Rule 9.110 of the Florida Rules of Appellate Procedure with the clerk of the Department of Environmental Protection in the Office of General Counsel (Mail Station #35, 3900 Commonwealth Boulevard, Tallahassee, Florida, 32399-3000) 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 Miami-Dade County Department of Regulatory and Economic Resources (RER), Division of Environmental Resources Management, Air Quality Management.

Executed in Miami-Dade County, Florida

_____ _____

H. Patrick Wong, Chief (Date)
Air Quality Management

**CERTIFICATE OF SERVICE**

The undersigned duly designated deputy agency clerk hereby certifies that this Final Air Permit package (including the Final Determination and Final Permit) was sent by certified U.S. mail and/or 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 _____ to the persons listed below.

Richard Gilbert, VP Operations, Noven Pharmaceuticals, Inc., 11960 SW 144 Street, Miami, FL 33186 [rgilbert@noven.com]

Jacob de Vries, Director, Engineering, Noven Pharmaceuticals, Inc., 11960 SW 144 Street, Miami, FL 33186 [jdevries@noven.com]

James Show, VP Engineering, Grove Scientific & Engineering Co., 6140 Edgewater Drive, Suite F, Orlando, FL 32810 [J_SSHOW@bellsouth.net]

Linda Brien, Florida Department of Environmental Protection, Southeast District Office [Linda.Brien@dep.state.fl.us]

Clerk Stamp

**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.

_____ _____

(Clerk) (Date

## FACILITY AND PROJECT DESCRIPTION

### Proposed Project

The applicant requests an air construction permit for the replacement of the existing East Coater thermal oxidizer with a recuperative thermal oxidizer (RCO).

This project includes the following emissions unit(s).

**Facility ID No. 0250616**

| ID No. | Emission Unit Description |
|---|---|
| 001 | East Coater: The coating process is composed of a coating knife roller system and an oven, along with other ancillary equipment. An enclosure is in place in front of the oven designed to surround the coater and web. The captured VOC generated during this process are controlled by a Glenro Model No. 2120078 Recuperative Thermal Oxidizer (RCO) rated at 4,000 SCFM, $1,400^0$ F operating temperature, 98% design destruction efficiency, and a maximum throughput rate of 77 lbs/hr. |

## FACILITY REGULATORY CLASSIFICATION

- The facility is not a major source of hazardous air pollutants (HAP).
- The facility has no 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 213, F.A.C.
- The facility is not a major stationary source in accordance with Rule 62-212.400(PSD), F.A.C.
- This facility is a synthetic minor, Non-Title V source of air pollution.

## SECTION 2. ADMINISTRATIVE REQUIREMENTS

1. Permitting Authority: The permitting authority for this project is the Miami-Dade County Department of Regulatory and Economic Resources (RER), Division of Environmental Resources Management, Air Quality Management. The RER's mailing address is: 701 NW 1 Court, Suite 400, Miami, Florida 33136. The RER's telephone number is 305/372-6925. All documents related to applications for permits to operate an emissions unit shall be submitted to the RER, Division of Environmental Resources Management, Air Quality Management.

2. Compliance Authority: All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the RER, Division of Environmental Resources Management, Air Quality Management. The mailing address of the RER, Division of Environmental Resources Management, Air Quality Management is: 701 NW 1 Court, Suite 400, Miami, Florida 33136. The RER, Division of Environmental Resources Management, Air Quality Management's telephone number is 305/372-6925.

3. Appendices: The following Appendices are attached as part of this permit:
   a. Appendix A. Citation Formats and Glossary of Common Terms;
   b. Appendix B. General Conditions;
   c. Appendix C. Common Conditions.
   d. Appendix D. Common testing requirements. (If applicable)

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, and Chapter 24, Code of Miami-Dade County. 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 RER or Florida Department of Environmental Protection (FDEP) may require the permittee to conform to new or additional conditions. The RER or FDEP shall allow the permittee a reasonable time to conform to the new or additional conditions, and on application of the permittee, the RER or FDEP may grant additional time.
   [Rule 62-4.080, F.A.C.]

6. Modifications: The permittee shall notify the RER upon commencement of construction. No new emissions unit shall be constructed and no existing emissions unit shall be modified without obtaining an air construction permit from the RER. 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. Source Obligation:
   (a) At such time that a particular source or modification becomes a major stationary source or major modification (as these terms were defined at the time the source obtained the enforceable limitation) solely by virtue of a relaxation in any enforceable limitation which was established after August 7, 1980, on the capacity of the source or modification otherwise to emit a pollutant, such as a restriction on hours of operation, then the requirements of subsections 62-212.400(4) through (12), F.A.C., shall apply to the source or modification as though construction had not yet commenced on the source or modification.

(b) At such time that a particular source or modification becomes a major stationary source or major modification (as these terms were defined at the time the source obtained the enforceable limitation) solely by exceeding its projected actual emissions, then the requirements of subsections 62-212.400(4) through (12), F.A.C., shall apply to the source or modification as though construction had not yet commenced on the source or modification.

[Rule 62-212.400(12), F.A.C.]

8. Application for Air Operation Permit: This permit authorizes construction and/or installation of the permitted emission unit(s) and initial operation to determine compliance with the FDEP and the RER rules. **An operation permit is required for regular operation of the permitted emission units.** The owner or operator shall apply for and receive an operation permit prior to expiration of this permit. An application for an operation permit shall be submitted to the Miami-Dade County Department of Regulatory and Economic Resources, Division of Environmental Resources Management, Air Quality Management. To apply for an operation permit, the applicant shall submit the appropriate application fee and, in triplicate, the appropriate application form, a certification that construction was completed with a notation of any deviations from the conditions on the construction permit, compliance test results, and such additional information as the RER may by law require.
[Rule 62-4.030, 62-4.050, 62-4.220, and 62-210.300 F.A.C.]

9. Extension of This Permit: The expiration date of this construction permit may be extended upon request of the owner or operator and submission of the appropriate fee to the Miami-Dade County Department of Regulatory and Economic Resources, Division of Environmental Resources Management, Air Quality Management **at least 60 days prior** to the expiration date of this permit.
[Rule 62-4.030, 62-4.050, 62-4.070(3), and 62-4.220 F.A.C.]

10. Annual Operating Report Required: The Annual Operating Report (DEP Form No. 62-210.900(5)) shall be completed each year and submitted to the Miami Dade County Department of Regulatory and Economic Resources, Division of Environmental Resources Management, Air Quality Management or submitted electronically to the FDEP by April 1 of the following year.
[Rule 62-210.370(3) F.A.C.]

11. Waste Disposal: The owner or operator shall treat, store, and dispose of all liquid, solid and hazardous wastes in accordance with all applicable Federal, State and Local regulations.

This section of the permit addresses the following emissions unit(s).

| ID No. | Emission Unit Description |
|---|---|
| 001 | East Coater: The coating process is composed of a coating knife roller system and an oven, along with other ancillary equipment. An enclosure is in place in front of the oven designed to surround the coater and web. The captured VOC generated during this process are controlled by a Glenro Model No. 2120078 Recuperative Thermal Oxidizer (RCO) rated at 4,000 SCFM, $1,400^0$ F operating temperature, 98% design destruction efficiency, and a maximum throughput rate of 77 lbs/hr. |

**PERFORMANCE RESTRICTIONS AND EMISSIONS STANDARDS**

1. Visible Emissions (VE): Visible emissions shall not exceed 5% opacity from the RCO except that visible emissions not exceeding 20% opacity are allowed for up to six (6) minutes in any one hour period.
   [Rule 62-4.070(3), F.A.C., Requested by Applicant in Application received January 21, 2013]

2. Facility-Wide VOC Emissions: Emissions of volatile organic compounds (VOCs), including hazardous air pollutants (HAPs), shall not equal or exceed 100 tons in any consecutive 12-month period.
   [Rule 62-4.070(3) F.A.C.]

3. Facility-Wide HAP Emissions: Total emissions of all hazardous air pollutants (HAPs) shall not equal or exceed 25 tons in any consecutive 12-month period.
   [Rule 62-4.070(3) F.A.C.]

4. Facility-Wide Individual HAP Emissions: Emissions of any individual hazardous air pollutant (HAP) shall not equal or exceed 10 tons in any consecutive 12-month period.
   [Rule 62-4.070(3) F.A.C.]

5. Emissions Limiting Standards: No owner or operator of a fabric coating line or a vinyl coating line subject to Rule 62-296.504, F.A.C., may cause, allow, or permit the discharge into the atmosphere of any volatile organic compounds in excess of 3.8 pounds per gallon of coating (0.46 kilograms per liter), excluding water, delivered to a coating applicator from a vinyl coating line.
   [Rule 62-296.504(2)(a)2, F.A.C., and Requested by Applicant in Application received January 21, 2013]

6. Vinyl Coating Emissions Limits: The permittee shall achieve the required emissions limiting standards under Rule 62-296.504(2) by:
   a. The application of low solvent content coating technology; or
   b. Incineration.
   [Rule 62-296.504(3) F.A.C.]

7. Allowable Fuel: Fuel burned shall be limited to natural gas.
   [Rule 62-4.070(3), F.A.C.]

8. Hours of Operation: The referenced emission units(s) may operate 24 hours/day, 7 days/week for 52 weeks/year resulting in 8,760 hours in any consecutive 12-month period.
   [Rules 62-4.070(3) and 62-210.200(PTE), F.A.C.]

9. Control Technology: The emissions limiting standards under Rule 62-296.504 F.A.C. and Section 3, Condition 5 of this permit, shall be achieved by incineration, provided that 90 percent of the VOCs (VOC measured as total combustible carbon) which enter the RCO are oxidized to carbon dioxide and water.
[Rule 62-296.504(3)(b) F.A.C]

10. Operating Temperature: Whenever the coating line is in operation, the RCO shall be on, and a minimum operating temperature of $1400^0$F shall be maintained.
[Rule 62-4.070(3) F.A.C.]

**COMPLIANCE MONITORING, TESTING, REPORTING AND RECORDKEEPING RQUIREMENTS**

11. Tests Required and Frequency: The permittee shall test this emissions unit initially and within sixty (60) days prior to the expiration of the operating permit for Visible Emissions, using EPA Method 9, and for Volatile Organic Compounds, using EPA Method 25 or 25A.
[Rules 62-4.070(3) and 62-297 F.A.C.]

12. Control Equipment: Since this facility employs a destructive control device to achieve the emission limiting standard, prior to the expiration of this construction permit the permittee shall verify that the control system meets the criteria for Permanent Total Enclosure in accordance with EPA Method 204 (adopted and incorporated by reference at Rule 62-204.800 F.A.C.) or conduct VOC Capture Efficiency testing, in accordance with Rule 62-297.450 VOC Capture Efficiency Test Procedures. The results obtained by EPA Method 204 must be submitted to the RER for approval prior to testing. The capture efficiency of the "enclosure" shall be determined, including connecting ductwork to the thermal oxidizer. A test protocol shall be submitted to RER at least thirty (30) days prior to the scheduled test date.
[Rule 62-297.440(7), 62-297.450 F.A.C.]

13. Permanent Total Enclosure Verification Method and Procedures: To demonstrate compliance with the criteria for Permanent Total Enclosure, the permittee shall verify that each of the following criteria is met using EPA Method 204.
    (1) Any natural draft opening (NDO) shall be at least four equivalent opening diameters from each VOC emitting point unless otherwise specified by the RER.
    (2) The total area of all NDOs shall not exceed 5 percent of the surface area of the enclosure's four walls, floor, and ceiling.
    (3) The average facial velocity (FV) of air through all NDOs shall be at least 3,600 m/hr (200 fpm). The direction of air flow through all NDOs shall be into the enclosure.
    (4) All access doors and windows whose areas are not included in (2) above and are not included in the calculation in (3) above shall be closed during routine operation of the process.
    (5) All VOC emissions must be captured and contained for discharge through a control device.

    [Rule 62-297.440(7), Rule 62-4.070(3) F.A.C.]

14. Destruction Efficiency Test Methods and Procedures: To demonstrate compliance with the emission limiting standards of this permit, the permittee shall conduct RCO destruction efficiency testing on this emissions unit initially, and within sixty (60) days prior to the submittal of an application for air operating permit renewal. The compliance tests shall consist of the following test methods and procedures, shall meet all applicable requirements of Rule 62-297 F.A.C, and results shall be included with any required permit applications.

a. RCO inlet and outlet gas concentrations shall be determined using EPA Method 25 or 25A or Attachment 3 of EPA 450/2-78-041, incorporated and adopted by reference in Chapter 62-297, F.A.C.
b. VOC content of vinyl coatings shall be determined by obtaining and analyzing a representative sample of vinyl coatings used during the destruction efficiency tests in accordance with EPA Method 24 or 24A.
c. The total amount of vinyl coatings, solvents, and all VOC containing materials used during the compliance tests shall be documented.
d. A report indicating the results of the required stack tests shall be filed with the RER no later than forty-five (45) days after the last sampling run is completed. The report shall provide sufficient detail on the tested emissions unit, and the procedures used to allow the RER to determine if the tests were properly conducted and if the test results were properly computed. At a minimum, the test report shall provide the applicable information cited in Chapter 62-297.310(8). In addition, the test report shall include the following:
   1) Destruction Efficiency Test For each Emissions Unit: For each run and the three run average, determine the following:
   - Destruction efficiency of VOC/HAP per hour to the RCO based on the following equation

$$\% \text{ Destruction Efficiency} = \frac{(VOC_{IN} - VOC_{OUT})}{(VOC_{IN})} \times 100\%$$

   - Inlet pounds of VOC/HAP per hour to the RCO ($VOC_{IN}$)
   - Outlet pounds of VOC/HAP per hour from the RCO ($VOC_{OUT}$)
   - VOC process rate in pounds of VOC/HAP per hour
   - Temperature ($^0$F) of the inlet to and the outlet from the RCO.
   - A general description of the condition of the control equipment to include the last date of thorough maintenance inspection, repairs made since last test, and changes to the equipment or processes made since the last test.

[Rule 62-296.504(4)(b)1, F.A.C.; Rule 62-4.070(3), F.A.C.]

15. Non-destructive: The test method for VOCs shall be EPA VOC Capture Efficiency Test Procedures Rule 62-297.440(7) F.A.C. The sampling time for each capture efficiency test run shall be at least 8 hours, unless otherwise approved by the Florida Department of Environmental Protection (FDEP) pursuant to Rule 62-297.620 F.A.C.
[Rule 62-296.504(4)(b)2 F.A.C.]

16. Alternate Procedure(s) Request: The permittee may obtain approval of alternate testing procedures according to items a through e below:
   a. Submit a request in writing for a determination by the FDEP Secretary of his/her designee that any requirement relating to emissions test procedures, methodology, equipment, or test facilities shall not apply to such emissions unit and request approval of an alternate procedure or requirements.
   b. The request shall set forth the following information, at a minimum:
      1) Specific emissions unit and permit number, if any, for which exception is requested.
      2) The specific provision(s) of this permit from which an exception is sought.
      3) The basis for the exception, including but not limited to any hardship, which would result from compliance with the provisions of this permit.
      4) The alternate procedure(s) or requirement(s) for which approval is sought and a demonstration that such alternate procedure(s) or requirement(s) shall be adequate to demonstrate compliance with applicable emissions limiting standards contained in the rules of the FDEP or any permit issued pursuant to those rules.

c. The Secretary of his/her designee shall specify by order each alternate procedure of requirement approved for an individual emissions unit source in accordance with 62-297.620 F.A.C. or shall issue an order denying the request for such approval. The FDEP order shall be final agency action, reviewable in accordance with Section 120.57, Florida Statutes.
d. The permittee shall submit such request in advance of the actual test date to allow sufficient time for FDEP to process such request.
e. The permittee shall submit copies of all such correspondence to the RER Air Quality Management only after FDEP approval has been obtained.

[Rule 62-297.620 F.A.C.; Rule 62-4.070(3) F.A.C.]

17. Modification: If any physical or operational change is made to the control system, the permittee shall notify the RER Air Quality Management within ten (10) working days after making such change. The RER shall require the permittee of the affected activity, process, or emissions unit to conduct a new capture efficiency test if the RER has reason to believe (based on engineering calculations or empirical evidence) that a physical or operational change made to the capture system has decreased the overall emissions reduction efficiency of the system.
[Rule 62-4.070(3), F.A.C.]

18. Monitoring Equipment: Monitoring equipment shall continuously monitor and record the Thermal Oxidizer chamber temperatures. The permittee shall operate, maintain, and calibrate the monitoring equipment in accordance with the manufacturer's recommendations.
[Rule 62-4.070(3) F.A.C.]

19. Test Report: The report shall indicate the results of the tests in the same form and units of measure as the applicable emission standard. The VOC content of the adhesive, the process rate of the adhesive, the capture efficiencies of the enclosure and the thermal oxidizer destruction efficiency shall be used to determine the emission level of the coating operation in pounds of VOCs per gallon (kilograms per liter) of coating, excluding water, delivered to the coating applicator. The results of the tests and this calculation shall determine whether or not the facility is in compliance with the emissions limiting standards.
The facility shall, for the following parameters, indicate the normal operating conditions for the equipment, the actual operating conditions during each test run and the method of determination:
    1) Oxidizer temperature ($^0$F)
    2) Process rate (gallons of adhesive per hour)
    3) Production rate (patches per hour)

[Rule 62-4.070(3) F.A.C.]

20. VOC Content and Emissions: The owner or operator shall determine the VOC content of all materials, including solvents, and shall monitor the usage of such materials at the referenced emission unit(s), by recording and maintaining the following information:
    a. The VOC content for each material containing or emitting VOCs.
    b. The material utilization rate on a monthly basis, for all materials containing or emitting VOCs used at the referenced emission unit(s).
    c. The total monthly VOC emission rates for each material, calculated from the monthly material utilization rates and the VOC content, calculated for the preceding month no later than 10 days after the end of that month.
    d. A rolling consecutive 12-month total emission rate for VOCs, calculated from the monthly totals for the previous twelve calendar months.

[Rule 62-4.070(3) F.A.C.]

21. Individual & Total HAP Content and Emissions: The owner or operator shall determine the total and individual HAP contents of all materials, including solvents, and shall monitor the usage of such materials at the referenced emission unit(s), by recording and maintaining the following information:
    a. The individual and total HAP contents for each material containing or emitting HAPs.
    b. The material utilization rate on a monthly basis, for all materials containing or emitting HAPs used at the referenced emission unit(s).
    c. The individual and total monthly HAP emission rates for each material, calculated from the monthly material utilization rates and the individual and total HAP content, calculated for the preceding month no later than 10 days after the end of that month.
    d. A rolling consecutive 12-month total emission rate for individual and total HAPs, calculated from the monthly totals for the previous twelve calendar months.

    [Rule 62-4.070(3) F.A.C.]

22. RCO Temperatures: The permittee shall record and maintain records of the chamber temperatures from the monitoring equipment for the RCO, and they shall be made available to RER personnel for review upon request.
    [Rule 62-4.070(3) F.A.C.]

23. Equipment Calibration: The permittee shall maintain the date, the name of the technician, and the procedures for performing the calibration on the continuous temperature monitoring system. Such records shall be kept in a maintenance log and made available to RER personnel for review upon request. Additionally, maintenance and repair activities on the RCO shall be documented and included in the maintenance log.
    [Rule 62-4.070(3) F.A.C.]

24. Supporting Documentation: The owner or operator shall maintain supporting documentation, such as Material Safety Data Sheets, purchase orders, usage and disposal records, a summary of any maintenance or repairs performed on the VOC capture system, etc., and shall include sufficient information to determine compliance. The log and documents shall be kept at the facility and made available for RER inspection for a minimum of three (3) years from the date of such records. Monthly logs shall be completed within 10 calendar days after completion of the preceding month.
    [Rule 62-4.070(3) F.A.C.]