

**NORTH CAROLINA DIVISION OF
AIR QUALITY**

Air Permit Review

Permit Issue Date: XX/XX/2005

Region: Raleigh Regional Office
County: Wilson
NC Facility ID: 9800185
Inspector's Name: Will Wike
Date of Last Inspection: 11/16/2004
Compliance Code: 3/In Compliance - Inspection

Facility Data			Permit Applicability (this application only)
Applicant (Facility's Name): Eon Pharma, LLC Facility Address: Eon Pharma, LLC 4700 Eon Drive Wilson, NC 27893 SIC: 2834 / Pharmaceutical Preparations NAICS: 325412 / Pharmaceutical Preparation Manufacturing Facility Classification: Before: Title V After: Title V Fee Classification: Before: Title V After: Title V			SIP: NSPS: NESHAP: PSD: PSD Avoidance: NC Toxics: 112(r): Other:
Contact Data			Application Data
Facility Contact	Authorized Contact	Technical Contact	Application Number: 9800185.04B Date Received: 10/01/2004 Application Type: Modification Application Schedule: TV-Significant Existing Permit Data Existing Permit Number: 08082/T11 Existing Permit Issue Date: 08/10/2004 Existing Permit Expiration Date: 09/30/2006
William Conover Director of Engineering (252) 234-2222 4700 Eon Drive Wilson, NC 27893	Michael Doelling Facility Manager (252) 234-2204 4700 Eon Drive Wilson, NC 27893	William Conover Director of Engineering (252) 234-2222 4700 Eon Drive Wilson, NC 27893	
Review Engineer: Jeff Twisdale Review Engineer's Signature: _____ Date: _____		Comments / Recommendations: Issue 08082/T12 Permit Issue Date: XX/XX/2005 Permit Expiration Date: 09/30/2006	

1. Introduction

This application is a request to incorporate the matrix patch line (ID No. ES-MPL) into the Title V Operating Permit. The Division of Air Quality (DAQ) received the application on October 14, 2004 and deemed the application complete. The application has been duly signed by the principal executive officer, and includes appropriate application forms, processing fee of \$834, etc. The local zoning consistency determination request was not required since no new construction coincides with this application.

The application will be processed per 15A NCAC 2Q .0516 "Significant Permit Modification." Because the previous modification to the permit did not contravene or conflict with any existing permit condition, the processing route for this application was per 2Q .0501(c), as allowed under 2Q .0516(d). Also, as advised by DAQ and agreed by the company (through their consultant, Trigon Engineering Consultants, Inc.), the previous modification was processed through a "two-step" route, which is allowed under 2Q .0501(c)(2). The construction and operation permit was issued pursuant to the provisions of 2Q .0300. Subsequent to the issuance of the construction and operation permit, the Permittee submitted a new application to modify the revised permit, within 12 months after commencing operation, to satisfy the requirements of 2Q .0500.

2. Facility Description

Eon Pharma, LLC (EON) operates a generic pharmaceutical manufacturing facility on Eon Drive in Wilson, Wilson County, NC. The facility contracts with different companies to make their products. The facility is operating under the air permit 08082T11. This permit was issued on August 10, 2004 and is currently scheduled to expire on September 30, 2006.

The permitted equipment includes the following: three natural gas-fired boilers, one fluid dryer process (four fluid bed dryers), one coating process (five coating pans), four drying tray ovens, one matrix patch line, and two diesel-fired emergency generators/peak shaving units.

The facility is a Title V major source, currently for volatile organic compounds (VOC) only. After this revision, the facility will remain a major source under Title V for VOCs.

3. Application Chronology

For complete details on the processing events for this application, please refer to the "Comprehensive Application Report for 9800185.04B."

4. Permit Modification/Changes

Matrix Patch Line (ID No. ES-MPL)

EON recently installed a new process to manufacture dermal delivery (skin patch) pharmaceutical products known as the matrix patch line (ID No. ES-MPL). The process began operation on October 3, 2003 after construction was allowed through a 2Q .0501(c)(2) modification under air permit 08082T10. Since the process is operating, the notation for construction (***) of this source will be removed along with the notification requirements. The same applicable regulations and other existing conditions will continue to apply (see below).

The matrix patch line (ID No. ES-MPL) is subject to the requirements of 2D .0958 and .1806, and 2Q .0317 (avoidance of 2D .0530 and 2D .1111) and .0711.

15A NCAC 2D .0958: Work Practices for Sources of Volatile Organic Compounds

This facility is already subject to 2D .0958. Compliance will be demonstrated through work practice standards. The facility has been shown to be in compliance with 2D .0958 in previous compliance inspections. Compliance is expected with this requirement for the emission source.

15A NCAC 2D .1806: Control and Prohibition of Odorous Emissions

Pursuant to 2D .1806(g) the facility shall not emit objectionable odors beyond the property line. Similar equipment at this facility has been inspected in the past with no odors noted. It is not expected that objectionable odors will be associated with this process. Therefore, compliance with 2D .1806 is expected.

15A NCAC 2Q .0711: Emission Rates Requiring a Permit

This emission source does emit an NC Toxic Air Pollutant, ethyl acetate. The 2Q .0711 exemption rate for modeling is 36 lb/hr. The expected emission rate for the equipment is 11.60 lb/hr. No other equipment at the facility emits ethyl acetate. Therefore, it is expected that the equipment will be in compliance with 2Q .0711. Please refer to Section 6 for additional details on the facility-wide limitations for toxic air pollutants.

15A NCAC 2Q .0317: Avoidance Conditions

In accordance with 2Q .0317(a)(1), in the existing permit, the Permittee has taken a PSD avoidance limit to restrict the potential to emit for VOC emissions below 250 tons/yr. Note that this emission limit accounts for VOC emissions from all permitted sources except boilers. The matrix patch line operates under the same PSD avoidance condition.

Similarly, in accordance with 2Q .0317(a)(5), in order to avoid complying with "pharmaceutical production" MACT regulation, the Permittee has taken a MACT avoidance limit in the existing permit, to restrict the potential to emit for HAP emissions below 10/25 tons/yr on a facility-wide basis. Again, the matrix patch line operates under the same MACT avoidance condition.

Seed Coater (ID No. ES-CP3) and Associated Bagfilter (ID No. DC-18) & HEPA Filter (ID No. HEPA-18)

EON also completed installation of a seed coater (ID No. ES-CP-3) on January 20, 2003 that was processed as a 502(b)(10) modification via an application filed on July 8, 2002. Since the equipment has been installed and is ready for operation, the notation for construction (*) of this source will be removed along with the other notification requirements. The same applicable regulations and other existing conditions will continue to apply.

5. NSPS, NESHAPS, PSD, Attainment Status, 112(r), and CAM

NSPS

The matrix patch line is not subject to any NSPS regulations.

NESHAP/MACT

The matrix patch line is not subject to any MACT regulations. As indicated above, the facility has taken a MACT avoidance limit in the existing permit to avoid the "pharmaceutical production" MACT regulation. As indicated above, all existing and new equipment will continue to operate under this MACT avoidance limit.

PSD

The County of Wilson is in attainment of all criteria pollutants. The facility is a "250 tons" category source and is currently considered to be a minor stationary source under the PSD regulations for all criteria pollutants. As indicated above, the facility has taken a limit to restrict the potential to emit for VOC emissions below 250 tons per year threshold on a facility-wide basis. The permit includes the necessary monitoring/record keeping/reporting requirements for all existing and new emission sources: boilers, fluid bed dryers, coating pans, drying tray ovens, matrix patch line, and emergency generators.

The minor source baseline dates for PM-10, sulfur dioxide, and nitrogen oxides have been triggered for Wilson County. This modification does not result in any increase in emissions of PM-10, sulfur dioxide, and nitrogen oxides. Emissions tracking for these pollutants will not be required for PSD Class II increment purposes.

112(r)

This facility is not subject to Section 112(r) of the Clean Air Act requirements because it does not store any of the regulated substances in quantities above the thresholds in this rule.

CAM

The analysis on applicability to any CAM requirement is required at this time since this application is being processed as a significant modification of the Title V Operating Permit pursuant to 2Q .0516. However, since the matrix patch line (ID No. ES-MPL) does not have a control device, CAM does not apply.

6. Facility-wide Air Toxics

The facility has the potential to exceed the toxic pollutant emission rates (TPER) for methylene chloride. The existing permit emission limits emissions of methylene chloride assure compliance with its acceptable ambient level (AAL). Specifically, the permit restricts the hourly emissions from the four fluid bed dryers to total 36 lbs/hr and five coating pans to total 39 lbs/hr, with an operating limit of only one source (one from four fluid bed dryers or one from five coating pans) can use methylene chloride at any given time. In addition, the annual emissions of methylene chloride have been limited in the existing permit to 33,200 lbs/yr for four fluid bed dryers combined and 250,000 lbs/yr for five coating pans combined.

7. Statement of Compliance

The facility was last inspected by RRO (Will Wike) on November 16, 2004. The facility was appeared in compliance with all requirements of the permit during this inspection.

8. Facility Emissions Review

The following table represents facility-wide emissions:

Pollutant	Actual Emissions (tons per year)	Potential Emissions (tons per year)
Particulate (TSP)	0.24	3
Particulate (PM-10)	0.24	3
Carbon Monoxide	2.65	27.6
Nitrogen Oxides	3.16	54
Sulfur Dioxide	0.03	4.4
Volatile Organic Compounds	16.43	< 250
Methylene Chloride (single largest HAP)	1.59	< 10
HAP	2.72	< 25

9. Stipulation Review

- Revise insignificant activity list to add small generator and fire pump.
- Revise Section 1 Table to remove notation (* and **) for installed emission sources (ID Nos. ES-CP-3 and ES-MPL).
- Revise Section 2.1 C Heading/Table to remove notation (*) for installed emission sources (ID No. ES-CP-3).
- Revise Section 2.1 E Heading/Table to remove notation (**) for installed emission sources (ID No. ES-MPL).
- Revise Section 2.2 B Heading to remove notation (* and **) for installed emission sources (ID Nos. ES-CP-3 and ES-MPL).
- Revise Part II to remove the recently installed sources (ID Nos. ES-CP-3 and ES-MPL) and notation (* and **)
- Revise Part II to remove the notification requirements (Section 2 3. & 4.) for source (ID No. ES-CP-3).
- Revise Part II to remove the requirement to file an application (Section 2 5.) for source (ID No. ES-MPL).
- Include the latest version of General Conditions in Part I and Part II.

10. Conclusions, Comments, and Recommendations

- Per 2Q .0304(b) "Consistency Determination", the company had provided in the previous application a copy of the "stamped received on June 7, 2004" of the letter request to City of Wilson Planning Department for the consistency determination with the local zoning regulations. However, the local zoning consistency determination is not required at this time since no additional construction coincides with this application.
- The draft permit was sent to RRO and EON on January 7, 2005 for review. No comments were received.
- Per 2Q .0516(f), public participation pursuant to 2Q .0521 and EPA/Affected State review pursuant to 2Q .0522 are required. The draft permit will now be sent to public notice with a 30 day comment period.
- Recommend issuance of this air permit after completion of public notice and EPA review periods.