



Joseph E. Kernan
Governor

Lori F. Kaplan
Commissioner

100 North Senate Avenue
P. O. Box 6015
Indianapolis, Indiana 46206-6015
(317) 232-8603
(800) 451-6027
www.state.in.us/idem

June 4, 2004

Mr. Brian Griesemer
Eli Lilly and Company - Clinton Laboratories
P.O. Box 99
Clinton, Indiana 47842

Re: Minor Source Modification No:
165-18973-00009

Dear Mr. Griesemer:

Eli Lilly and Company - Clinton Laboratories applied for a Part 70 operating permit on August 21, 1996 for a pharmaceutical manufacturing plant. An application to modify the source was received on April 14, 2004. Pursuant to 326 IAC 2-7-10.5, the following emission units are approved for construction at the source:

- (a) One (1) Rotary Drum Vacuum Filter (RDVF), identified as C45FIL109, constructed in 2004, located in building C45, controlled by a carbon absorber (identified as CA140), and exhausting through stack PVC45AC140A.

The proposed Minor Source Modification approval will be incorporated into the pending Part 70 permit application pursuant to 326 IAC 2-7-10.5(l)(3). The source may begin operation upon issuance of the source modification approval.

Pursuant to Contract No. A305-0-00-36, IDEM, OAQ has assigned the processing of this application to Eastern Research Group, Inc., (ERG). Therefore, questions should be directed to Yu-Lien Chu, ERG, 1600 Perimeter Park Drive, Morrisville, North Carolina 27560, or call (919) 468-7871 to speak directly to Ms. Yu-Lien Chu. Questions may also be directed to Duane Van Laningham at IDEM, OAQ, 100 North Senate Avenue, P.O. Box 6015, Indianapolis, Indiana, 46206-6015, or call (800) 451-6027, and ask for Duane Van Laningham, or extension 3-6878, or dial (317) 233-6878.

Sincerely,
Original signed by

Paul Dubenetzky, Chief
Permits Branch
Office of Air Quality

Attachments
ERG/YC

cc: File - Vermillion County
U.S. EPA, Region V
Vermillion County Health Department
Air Compliance Section Inspector - Jim Thorpe
Compliance Data Section
Administrative and Development - Sara Cloe
Technical Support and Modeling - Michele Boner
Title V file - T165-6462-00009
Title V Reviewer - Trip Sinha



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PART 70 MINOR SOURCE MODIFICATION OFFICE OF AIR QUALITY

**Eli Lilly and Company - Clinton Laboratories
10500 South State Road 63
Clinton, Indiana 47842**

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this approval.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Minor Source Modification No.: 165-18973-00009	
Issued by: Original signed by Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: June 4, 2004

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SECTION A

SOURCE SUMMARY

This approval is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the emission units contained in conditions A.1 through A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this approval pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)][326 IAC 2-7-1(22)]

The Permittee owns and operates a stationary pharmaceutical manufacturing plant.

Responsible Official:	Plant Manager
Source Address:	10500 South State Road 63, Clinton, Indiana 47842
Mailing Address:	P.O. Box 99, Clinton, Indiana 47842
General Source Phone Number:	(765) 832-4781
SIC Code:	2833, 2834, 2879
County Location:	Vermillion
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Permit Program Major Source, under PSD Major Source, Section 112 of the Clean Air Act 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This stationary source is approved to construct and operate the following emission units and pollution control devices which are specifically regulated, as defined in 326 IAC 2-7-1(21):

- (a) One (1) Rotary Drum Vacuum Filter (RDVF), identified as C45FIL109, constructed in 2004, located in building C45, controlled by a carbon absorber (identified as CA140), and exhausting through stack PVC45AC140A.

A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

- (a) It is a major source, as defined in 326 IAC 2-7-1(22);
- (b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONSTRUCTION CONDITIONS

B.1 Definitions [326 IAC 2-7-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

B.3 Revocation of Permits [326 IAC 2-1.1-9(5)][326 IAC 2-7-10.5(i)]

Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

SECTION C GENERAL OPERATION CONDITIONS

C.1 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

- (a) Where specifically designated by this permit or required by an applicable requirement, any application form, report, or compliance certification submitted shall contain certification by a responsible official of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- (b) One (1) certification shall be included, using the attached Certification Form, with each submittal requiring certification.
- (c) A responsible official is defined at 326 IAC 2-7-1(34).

C.2 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]

- (a) If required by specific condition(s) in Section D of this permit, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) when operation begins, including the following information on each facility:
 - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The PMP extension notification does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (b) The Permittee shall implement the PMPs, including any required record keeping, as necessary to ensure that failure to implement a PMP does not cause or contribute to an exceedance of any limitation on emissions or potential to emit.
- (c) A copy of the PMPs shall be submitted to IDEM, OAQ, upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ, may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or contributes to any violation. The PMP does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation, Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for the unit.

C.3 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

(a) Permit amendments and modifications are governed by the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

Any such application shall be certified by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

(d) No permit amendment or modification is required for the addition, operation or removal of a nonroad engine, as defined in 40 CFR 89.2.

C.4 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.5 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

C.6 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided by statute or rule, or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission unit vented to the control equipment is in operation.

Compliance Requirements [326 IAC 2-1.1-11]

C.7 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

C.8 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

If required by Section D, all monitoring and record keeping requirements shall be implemented when operation begins. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment.

C.9 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]

Any monitoring or testing required by Section D of this permit shall be performed according to the provisions of 326 IAC 3, 40 CFR 60, Appendix A, 40 CFR 60 Appendix B, 40 CFR 63, or other approved methods as specified in this permit.

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

C.10 Emergency Provisions [326 IAC 2-7-16]

- (a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation.
- (b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:
- (1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;
 - (2) The permitted facility was at the time being properly operated;
 - (3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;
 - (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, and the Southwest Regional Office within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

IDEM, OAQ

Telephone No.: 1-800-451-6027 (ask for Office of Air Quality, Compliance Section) or,

Telephone No.: 317-233-5674 (ask for Compliance Section)

Facsimile No.: 317-233-5967

- (5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-7-5(3)(C)(ii) and must contain the following:

- (A) A description of the emergency;
- (B) Any steps taken to mitigate the emissions; and
- (C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

- (6) The Permittee immediately took all reasonable steps to correct the emergency.
- (c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
- (d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.
- (e) IDEM, OAQ, may require that the Preventive Maintenance Plans required under 326 IAC 2-7-4-(c)(i) be revised in response to an emergency.
- (f) Failure to notify IDEM, OAQ, by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-7 and any other applicable rules.
- (g) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.
- (h) The Permittee shall include all emergencies in the Quarterly Deviation and Compliance Monitoring Report.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

C.11 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

- (a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.
- (b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance.

C.12 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

- (a) The reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015

Indianapolis, Indiana 46206-6015

- (b) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.
- (c) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (d) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

SECTION D.1

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (a) One (1) Rotary Drum Vacuum Filter (RDVF), identified as C45FIL109, constructed in 2004, located in building C45, controlled by a carbon absorber (identified as CA140), and exhausting through stack PVC45AC140A.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.1.1 Volatile Organic Compounds (VOCs) [326 IAC 2-7-10.5] [326 IAC 8-1-6]

The potential VOC emissions from the proposed RDVF are less than 25 tons per year. Therefore, the requirements of 326 IAC 2-7-10.5(f) (Significant Source Modification) and 326 IAC 8-1-6 (BACT) are not applicable. Any change or modification which may increase the potential VOC emissions from the RDVF to greater than 25 tons/yr must be approved by the Office of Air Quality before any such change may occur.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR QUALITY

PART 70 SOURCE MODIFICATION CERTIFICATION

Source Name: Eli Lilly and Company - Clinton Laboratories
Source Address: 10500 South State Road, 63, Clinton, Indiana 47842
Mailing Address: P.O. Box 99, Clinton, Indiana 47842
Source Modification No.: 165-18973-00009

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this approval.

Please check what document is being certified:

- Test Result (specify) _____
- Report (specify) _____
- Notification (specify) _____
- Affidavit (specify) _____
- Other (specify) _____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Date:

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH
100 North Senate Avenue
P.O. Box 6015
Indianapolis, Indiana 46206-6015
Phone: 317-233-5674
Fax: 317-233-5967**

**PART 70 OPERATING PERMIT
EMERGENCY OCCURRENCE REPORT**

Source Name: Eli Lilly and Company - Clinton Laboratories
Source Address: 10500 South State Road, 63, Clinton, Indiana 47842
Mailing Address: P.O. Box 99, Clinton, Indiana 47842
Source Modification No.: 165-18973-00009

This form consists of 2 pages

Page 1 of 2

- ☛ This is an emergency as defined in 326 IAC 2-7-1(12)
- The Permittee must notify the Office of Air Quality (OAQ), within four (4) business hours (1-800-451-6027 or 317-233-5674, ask for Compliance Section); and
 - The Permittee must submit notice in writing or by facsimile within two (2) working days (Facsimile Number: 317-233-5967), and follow the other requirements of 326 IAC 2-7-16.

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A

Page 2 of 2

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO ₂ , VOC, NO _x , CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by: _____

Title / Position: _____

Date: _____

Phone: _____

A certification is not required for this report.

issued June 4, 2004

**Indiana Department of Environmental Management
Office of Air Quality**

**Technical Support Document (TSD) for a
Part 70 Minor Source Modification**

Source Background and Description

Source Name:	Eli Lilly and Company - Clinton Laboratories
Source Location:	10500 South State Road 63, Clinton, Indiana 47842
County:	Vermillion
SIC Code:	2833, 2834, 2879
Operation Permit No.:	T165-5462-00009
Operation Permit Issuance Date:	Pending
Minor Source Modification No.:	165-18973-00009
Permit Reviewer:	ERG/YC

The Office of Air Quality (OAQ) has reviewed a modification application from Eli Lilly and Company - Clinton Laboratories relating to the construction and operation of the following emission units:

- (a) One (1) Rotary Drum Vacuum Filter (RDVF), identified as C45FIL109, constructed in 2004, located in building C45, controlled by a carbon absorber (identified as CA140), and exhausting through stack PVC45AC140A.

History

On April 14, 2004, Eli Lilly and Company - Clinton Laboratories (referred to as "Eli Lilly") submitted an application to the OAQ requesting permission to replace the existing Rotary Drum Vacuum Filter (RDVF), which is part of the product recovery operations located at building C45, with a new similar unit. The source stated the existing RDVF has surpassed its life expectancy and needs to be replaced. Eli Lilly submitted a Part 70 permit application on August 21, 1996 and their draft Part 70 permit is currently in public notice.

The RDVF is an integral part of the Monensin animal health product recovery process that separates the Monensin sodium crystals from the slurry. VOC emissions occur from the evaporation of the processed material and the wash-out solvent (Amyl Alcohol). The source stated that this replacement will not increase the throughput rate of the existing product recovery operations because the upstream units are currently operating at their maximum capacity. Therefore, this replacement will not result in debottlenecking or increase utilization of other existing units.

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Commissioner that the Part 70 Minor Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on April 14, 2004.

Emission Calculations

The calculations submitted by the applicant have been verified and found to be accurate and correct.

Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source or emissions unit to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA.”

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	--
PM-10	--
SO ₂	--
VOC	11.9
CO	--
NO _x	--

Justification for Modification

The Part 70 operating permit is being modified through a Part 70 Minor Source Modification. This modification is being performed pursuant to 326 IAC 2-7-10.5 (d)(4)(B) as the potential to emit VOC is greater than 10 tons/yr, and less than 25 tons/yr.

County Attainment Status

The source is located in Vermillion County.

Pollutant	Status
PM-10	Attainment
SO ₂	Attainment
NO ₂	Attainment
Ozone	Attainment
CO	Attainment
Lead	Attainment

- (a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, VOC emissions are considered when evaluating the rule applicability relating to the ozone standards. Vermillion County has been designated as attainment or unclassifiable for ozone. Therefore, VOC emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.
- (b) Vermillion County has been classified as attainment or unclassifiable for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(c) Fugitive Emissions

Since this type of operation (a chemical process plant) is in one of the 28 listed source categories under 326 IAC 2-2, the fugitive particulate matter (PM) and volatile organic compound (VOC) emissions are counted toward determination of PSD applicability.

Source Status

Existing Source PSD Definition (emissions after controls, based on 8,760 hours of operation per year at rated capacity and/ or as otherwise limited):

Pollutant	Emissions (ton/yr)
PM	112
PM10	112
SO ₂	1,696
VOC	848
CO	247
NO _x	949

- (a) This existing source is a major stationary source because an attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is in one of the 28 listed source categories.
- (b) These emissions are based upon the OAQ 2002 emission inventory data submitted by the source.

Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

Process/facility	Potential to Emit (tons/year)						
	PM	PM-10	SO ₂	VOC	CO	NO _x	HAPs
Proposed RDVF	-	-	-	11.9	-	-	-
PSD Thresholds	25	15	40	40	100	40	NA

This modification to an existing major stationary source is not major because the emissions increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, the PSD requirements do not apply.

Federal Rule Applicability

- (a) There are no New Source Performance Standards (NSPS)(326 IAC 12 and 40 CFR Part 60) applicable to this modification.
- (b) There are no National Emission Standards for Hazardous Air Pollutants (NESHAPs)(326 IAC 14 and 40 CFR Part 63) applicable to this modification.
- (c) The proposed RDVF does not process, produce, or use HAP compounds that generate HAP emissions. Therefore, the proposed RDVF is not subject to the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Pharmaceuticals Production (326 IAC 20, 40 CFR Part 63.1250 - 63.1261, Subpart GGG).

- (d) This modification does not involve a pollutant-specific emission unit as defined in 40 CFR 64.1:
- (1) With the potential to emit before controls equal to or greater than the major source threshold;
 - (2) That is subject to an emission limitation or standard; and
 - (3) Uses a control device as defined in 40 CFR 64.1 to comply with that emission limitation or standard.

Therefore, the requirements of 40 CFR 64 (Compliance Assurance Monitoring) are not applicable to this modification.

State Rule Applicability - RDVF Unit

326 IAC 2-7-10.5(d) (Minor Source Modifications)

The potential to emit VOC from RDVF is less than 25 tons/yr. Therefore, the requirements of 326 IAC 2-7-10.5(f)(C) (Significant Source Modifications) are not applicable. Any change or modification which may increase the potential VOC emissions from the RDVF to greater than 25 tons/yr must be approved by the Office of Air Quality before any such change may occur.

326 IAC 8-1-6 (General Reduction Requirements for VOC Emissions)

The potential VOC emissions from the proposed RDVF are less than 25 tons per year. Therefore, the requirements of 326 IAC 8-1-6 (BACT) are not applicable. Any change or modification which may increase the potential VOC emissions from the RDVF to greater than 25 tons/yr must be approved by the Office of Air Quality before any such change may occur.

326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations)

The RDVF does not manufacture pharmaceutical products by chemical synthesis. Therefore, this equipment is not subject to the requirements of 326 IAC 8-5-3.

Compliance Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAQ, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-7-5. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within state and federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance monitoring requirements applicable to this modification are as follows:

1. The RDVF is controlled by a carbon absorber (CA140). However, this absorber is a voluntary control device. Therefore, there are no specifically applicable compliance monitoring requirements for the proposed RDVF.

Conclusion

The construction and operation of this proposed modification shall be subject to the conditions of the attached proposed Part 70 Minor Source Modification No. 165-18973-00009.