

Dwight Howard
Schwarz Pharma USA, Inc.
1101 "C" Avenue West
Freeman Field
Seymour, Indiana 47274

Re: Minor Source Modification No:
071-12424-00023

Dear Dwight Howard:

Schwarz Pharma USA, Inc. applied for a Part 70 operating permit on November 14, 1996 for Pharmaceutical Manufacturing plant. An application to modify the source was received on June 27, 2000. Pursuant to 326 IAC 2-7-10.5 the following emission units are approved for construction at the source:

- (a) Phase IIIA production area, identified as emission unit-02 (EU-02). This area is already permitted by T071-11653 Minor Source Modification for manufacture of several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02. The modification consist of 660 lbs/batch of Ethanol coating to dry process.

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.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter call (800) 451-6027, press 0 and ask for Gurinder Saini or extension 3-0203, or dial (317) 233-0203.

Sincerely,

Paul Dubenetzky, Chief
Permits Branch
Office of Air Management

Attachments

GS

cc: File - Jackson County
U.S. EPA, Region V
Jackson County Health Department
Air Compliance Section Inspector - Joe Foyst
Compliance Data Section - Karen Nowak
Administrative and Development - Janet Mobley
Technical Support and Modeling - Michele Boner

PART 70 MINOR SOURCE MODIFICATION OFFICE OF AIR MANAGEMENT

**Schwarz Pharma USA, Inc.
1101 "C" Avenue West, Freeman Field
Seymour, Indiana 47274**

(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.

Second Minor Source Modification No.: 071-12424-00023

Issued by:
Paul Dubenetzky, Branch Chief
Office of Air Management

Issuance Date:

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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 Management (OAM). 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)]

The Permittee owns and operates a pharmaceutical plant.

Responsible Official: John Lee
Source Address: 1101 "C" Avenue West, Freeman Field, Seymour, Indiana 47274
Mailing Address: 1101 "C" Avenue West, Freeman Field, Seymour, Indiana 47274
Phone Number: (812) 523-5405
SIC Code: 3931
County Location: Jackson County
County Status: Attainment for all criteria pollutants
Source Status: Part 70 Permit Program
Minor Source, under PSD Rules;

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:

- (a) Phase IIIA production area, identified as emission unit-02 (EU-02). This area is already permitted by T071-11653 Minor Source Modification for manufacture of several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02. The modification consist of 660 lbs/batch of Ethanol coating to dry process.

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 Permit No Defense [IC 13]

This approval to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

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

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

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

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

B.4 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 approval or required by an applicable requirement, any application form, report, or compliance certification submitted under this approval 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, on the attached Certification Form, with each submittal.
- (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 approval, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days after issuance of this approval, 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;
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If due to circumstances beyond its control, the PMP 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 Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

- (b) The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that failure to implement the Preventive Maintenance Plan does not cause or contribute to a violation of any limitation on emissions or potential to emit.
- (c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM. IDEM, OAM, may require the Permittee to revise its Preventive Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation.

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

- (a) The Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.
- (b) Any application requesting an amendment or modification of this approval shall be submitted to:

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

Any such application should be certified by the "responsible official" as defined by 326 IAC 2-7-1(34) only if a certification is required by the terms of the applicable rule

- (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)]

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 Exemptions), opacity shall meet the following, unless otherwise stated in this approval:

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

Except as otherwise provided in this approval, all air pollution control equipment listed in this approval 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.

Testing Requirements [326 IAC 2-7-6(1)]

C.6 Performance Testing [326 IAC 3-6][326 IAC 2-1.1-11]

- (a) Compliance testing on new emission units shall be conducted within 60 days after achieving maximum production rate, but no later than 180 days after initial start-up, if specified in Section D of this approval. All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this approval, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAM.

A test protocol, except as provided elsewhere in this approval, shall be submitted to:

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

no later than thirty-five (35) days prior to the intended test date. The Permittee shall submit a notice of the actual test date to the above address so that it is received at least two weeks prior to the test date.

- (b) All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the IDEM, OAM, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.

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

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

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

Compliance with applicable requirements shall be documented as required by this approval. All monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

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

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

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

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

- (a) With the exception of performance tests conducted in accordance with Section C- Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment is operating at normal representative conditions.
- (b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.
- (c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.
- (d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.
- (e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.

- (f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

C.9 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

- (a) Records of all required monitoring data and support information 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 kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. 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 written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.
- (b) Records of required monitoring information shall include, where applicable:
 - (1) The date, place, and time of sampling or measurements;
 - (2) The dates analyses were performed;
 - (3) The company or entity performing the analyses;
 - (4) The analytic techniques or methods used;
 - (5) The results of such analyses; and
 - (6) The operating conditions existing at the time of sampling or measurement.
- (c) Support information shall include, where applicable:
 - (1) Copies of all reports required by this approval;
 - (2) All original strip chart recordings for continuous monitoring instrumentation;
 - (3) All calibration and maintenance records;
 - (4) Records of preventive maintenance shall be sufficient to demonstrate that failure to implement the Preventive Maintenance Plan did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this approval, and whether a deviation from an approval condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.
- (d) All record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance.

C.10 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

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

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

- (b) Unless otherwise specified in this approval, any notice, report, or other submission required by this approval 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, OAM, on or before the date it is due.
- (c) Unless otherwise specified in this approval, any semi-annual report shall be submitted within thirty (30) days of the end of the reporting period. The report does not 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 approval and ending on the last day of the reporting period.

SECTION D.1 FACILITY OPERATION CONDITIONS

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

Insignificant Activities:

- (a) Phase IIIA production area, identified as emission unit-02 (EU-02). This area is already permitted by T071-11653 Minor Source Modification for manufacture of several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02. The modification consist of 660 lbs/batch of Ethanol coating to dry process.

Emission Limitations and Standards

D.1.1 New Facilities: General reduction requirements [326 IAC 8-1-6]

Any change or modification which would increase the potential to emit VOC from Phase IIIA production area to twenty five (25) tons per year, shall obtain prior approval from IDEM, OAM and shall be subject to the requirements of 326 IAC 8-1-6.

Compliance Determination Requirements

D.1.2 Testing Requirements [326 IAC 2-8-5(a)(1), (4)][326 IAC 2-1.1-11]

The Permittee is not required to test this facility by this permit. However, IDEM may require compliance testing when necessary to determine if the facility is in compliance.

Record Keeping and Reporting Requirements

D.1.3 Record Keeping Requirements

There are no Record Keeping or Reporting Requirements.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR MANAGEMENT
COMPLIANCE DATA SECTION**

**PART 70 SOURCE MODIFICATION
CERTIFICATION**

Source Name: Schwarz Pharma USA, Inc.
Source Address: 1101 "C" Avenue West, Freeman Field, Seymour, Indiana 47274
Mailing Address: 1101 "C" Avenue West, Freeman Field, Seymour, Indiana 47274
Source Modification No.: 071-12424-00023

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:

- 9 Test Result (specify) _____
- 9 Report (specify) _____
- 9 Notification (specify) _____
- 9 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 Management

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

Source Background and Description

Source Name:	Schwarz Pharma USA, Inc.
Source Location:	1101 "C" Avenue West, Freeman Field, Seymour, Indiana 47274
County:	Jackson
SIC Code:	2834
Operation Permit No.:	T 071-7162-00023
Operation Permit Issuance Date:	pending under review
Second Minor Source Modification No.:	071-12424-00023
Permit Reviewer:	Gurinder Saini

The Office of Air Management (OAM) has reviewed a modification application from Schwarz Pharma USA, Inc. relating to the modification of the existing process in one of the production areas at their existing Pharmaceutical plant. The following is the proposed modification:

- (a) Phase IIIA production area, identified as emission unit-02 (EU-02). This area is already permitted by T071-11653 Minor Source Modification for manufacture of several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02. The modification consist of 660 lbs/batch of Ethanol coating to dry process.

History

On June 27, 2000, Schwarz Pharma USA, Inc., submitted an application to the OAM requesting to modify existing production area at their existing plant. Schwarz Pharma USA, Inc. submitted a Part 70 permit application 071-7162-00023 on November 14, 1996.

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 June 27, 2000.

Emission Calculations

The calculations submitted by the applicant have been verified and found to be accurate and correct. These calculations are provided in Appendix A page 1 of 1 of this document.

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 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. The PTE is based on 31 batches per year, as shown in Appendix A. 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	10.2
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), because the Volatile Organic Compounds (VOC) are emitted at a rate greater than 10 tons per year but less than 25 tons per year.

County Attainment Status

The source is located in Jackson County.

Pollutant	Status (attainment, maintenance attainment, or unclassifiable; severe, moderate, or marginal nonattainment)
PM-10	attainment
SO ₂	attainment
NO ₂	attainment
Ozone	attainment
CO	attainment
Lead	Not determined

- (a) Volatile organic compounds (VOC) and oxides of nitrogen (NO_x) are precursors for the formation of ozone. Therefore, VOC and NO_x emissions are considered when evaluating the rule applicability relating to the ozone standards. Jackson County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NO_x emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (b) Jackson County has been classified as attainment or unclassifiable for all the other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Source Status

Existing Source PSD or Emission Offset Definition (emissions after controls, based from the Airs Facility Subsystem Report dated January 21, 1999):

Pollutant	Emissions (tons/year)
PM	0.26
PM-10	0.26
SO ₂	0.05
VOC	65.6
CO	2.99
NO _x	11.97

- (a) This existing source is **not** a major stationary source because no attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is one of the 28 listed source categories.

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
Phase IIIA Production	-	-	-	10.2	-	-	-

This modification to an existing minor stationary source is not major because the emission increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

Federal Rule Applicability

- (a) New Source Performance Standards (NSPS):
 - (a) 40 CFR § 60.610, Subpart III - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.

This NSPS applies to each air oxidation reactor unit for which Construction, Modification or Reconstruction commenced after October 21, 1983 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Phase IIIA production area is not subject to this NSPS because it does not involve any chemical or compound production.

- (2) 40 CFR § 60.660, Subpart NNN - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.

This NSPS applies to each distillation unit for which Construction, Modification or Reconstruction commenced after December 30, 1983 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Phase IIIA production area is not subject to this NSPS because it does not involve any chemical or compound production.

There are no other New Source Performance Standards (NSPS)(326 IAC 12 and 40 CFR Part 60) applicable to this proposed modification.

- (b) There are no National Emission Standards for Hazardous Air Pollutants (NESHAPs)(326 IAC 14 and 40 CFR Part 63) applicable to this proposed modification.

State Rule Applicability - Individual Facilities

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

This rule applies to the manufacture of pharmaceutical products by chemical synthesis. It applies to all facilities emitting volatile organic compounds, including reactors, distillation units, dryers, storage of VOC, transfer of VOC, extraction equipment, filter, crystallizers, and centrifuges, that have potential to emit 15 pounds of VOC per day.

The Phase IIIA production are not subject to 326 IAC 8-5-3 because they don't involve any chemical synthesis. Phase IIIA production mainly involve coating medical dry product with Ethanol with potential to emit of 2.3 lbs/hour.

326 IAC 8-1-6 (New Facilities; General reduction requirements)

Since the Phase IIIA production is constructed after January 1, 1980 and the potential to emit VOC from the area is less than 25 tons per year, the requirements of 326 IAC 8-1-6 does not apply.

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, OAM, 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.

Conclusion

The construction of this proposed modification shall be subject to the conditions of the attached proposed Part 70 **Second Minor Source Modification No.071-12424-00023.**