



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

TO: Interested Parties / Applicant
DATE: May 18, 2007
RE: Baxter Pharmaceutical Solutions / 105-24671-00040
FROM: Nisha Sizemore
Chief, Permits Branch
Office of Air Quality

Notice of Decision – Approval

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to 326 IAC 2, this approval was effective immediately upon submittal of the application.

If you wish to challenge this decision, IC 4-21.5-3-7 requires that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) calendar days from the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER-AM.dot 03/23/06



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We make Indiana a cleaner, healthier place to live.

Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
(317) 232-8603
(800) 451-6027
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Ms. Kate Hamblin
Baxter Pharmaceutical Solutions, LLC
P.O. Box 3068
Bloomington, IN 47402

May 18, 2007

Re: 105-24671-00040
First Notice-Only Change to
MSOP No. 105-16441-00040

Dear Ms. Hamblin:

Baxter Pharmaceutical Solutions, LLC., was issued a Minor Source Operating Permit (MSOP) on March 5, 2004, for a stationary third party pharmaceutical manufacturing operation located at 927 South Curry Pike, Bloomington, Indiana 47403. On April 24, 2007, the Office of Air Quality (OAQ) received a letter from the source requesting that the permit be updated to indicate a change in the Authorized Individual (A.I.). IDEM has begun implementing a new procedure and will no longer list the name or title of the Authorized Individual (A.I.) in the permit document.

Pursuant to the provisions of 326 IAC 2-6.1-6, the permit is hereby revised as follows, with deleted language as ~~strikeouts~~ and new language **bolded**:

- (a) IDEM has begun implementing a new procedure and will no longer list the name or title of the Authorized Individual (A.I.) in the permit document. Section A.1 is updated as follows:

Authorized Individual: ~~_____ Lee Karras~~

- (b) The IDEM mailing address was revised throughout the permit to remove P.O. Box 6015 and to revise the zip code from ~~46206-6015~~ to **46204-2251**. All occurrences of IDEM mailing addresses have also been revised to include a mail code (MC) as follows:

Asbestos Section: **MC 61-52 IGCN 1003**
Compliance Branch: **MC 61-53 IGCN 1003**
Permits Branch: **MC 61-53 IGCN 1003**
Technical Support and Modeling Section: **MC 61-50 IGCN 1003**

All other conditions of the permit shall remain unchanged and in effect. Please find the enclosed copy of the revised entire permit for Steel Parts Manufacturing. 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, please contact Pam K. Way, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana, 46204-2251, at (317) 232-8427, or call (800) 451-6027, extension 2-8427.

Sincerely,
Original signed by

Nisha Sizemore, Chief
Permits Branch
Office of Air Quality

NS/pkw

Attachment: revised permit

cc: File - Monroe County
Monroe County Health Department
Air Compliance Section Inspector – Jennifer Schick
Compliance Data Section
Permits Administration and Development
Permit Review Section 5 - Pam K. Way
Billing, Licensing, and Training Section - Dan Stamatkin



Mitchell E. Daniels, Jr.
 Governor

Thomas W. Easterly
 Commissioner

100 North Senate Avenue
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**NEW SOURCE CONSTRUCTION PERMIT
 and
 MINOR SOURCE OPERATING PERMIT
 OFFICE OF AIR QUALITY**

**Baxter Pharmaceutical Solutions LLC
 927 South Curry Pike
 Bloomington, Indiana 47403**

(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 permit.

This permit is issued to the above mentioned company under the provisions of 326 IAC 2-1.1, 326 IAC 2-5.1, 326 IAC 2-6.1 and 40 CFR 52.780, with conditions listed on the attached pages.

Operation Permit No.: MSOP 105-16441-00040	
Original signed by Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: March 5, 2004 Expiration Date: March 5, 2009

First Minor Permit Revision No. 105-19185-00040, issued August 27, 2004

First Notice-Only Change No. 105-24671-00040	Pages Affected: Entire Permit
Original signed by: Nisha Sizemore, Chief Permits Branch Office of Air Quality	Issuance Date: May 18, 2007 Expiration Date: March 5, 2009

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SECTION A

SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 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 permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-5.1-3(c)] [326 IAC 2-6.1-4(a)]

The Permittee owns and operates a stationary third party pharmaceutical manufacturing operation.

Source Address:	927 South Curry Pike, Bloomington, Indiana 47403
Mailing Address:	P.O. Box 3068, Bloomington, Indiana 47402
General Source Phone:	812-333-0887
SIC Code:	2834
County Location:	Monroe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Minor Source, under PSD or Emission Offset Rules; Minor Source, Section 112 of the Clean Air Act

A.2 Emissions Units and Pollution Control Equipment Summary

The owner or operator of this stationary source is approved to construct and operate the following emissions units and pollution control devices:

- (a) One (1) pharmaceutical manufacturing operation consisting of:
- (1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;
 - (2) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging;
 - (3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;
 - (4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;
 - (5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging; and
 - (6) One (1) final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.
- (b) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as BR03 and BR04, located in Building A.

- (c) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as BR01 and BR02, located in Building A.
- (d) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as BR06 and BR07, located in Building C.
- (e) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as BR05, located in Building C.
- (f) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BR09, located in Building F.
- (g) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.
- (h) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.
- (i) One (1) 6.43 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.
- (j) Three (3) natural gas-fired boilers (identified as BR11, BR12, and BR13), each with a maximum heat input capacity of 14.7 MMBtu per hour. These units were installed in 2004.

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

This stationary source is not required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

- (a) It is not a major source, as defined in 326 IAC 2-7-1(22);
- (b) It is not an affected source under Title IV (Acid Deposition Control) of the Clean Air Act, as defined in 326 IAC 2-7-1(3); and
- (c) It is not 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 CONDITIONS

THIS SECTION OF THE PERMIT IS BEING ISSUED UNDER THE PROVISIONS OF 326 IAC 2-1.1 AND 40 CFR 52.780, WITH CONDITIONS LISTED BELOW.

B.1 Permit No Defense [IC 13]

This permit 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

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 2-1.1-1 shall prevail.

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

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

B.4 Revocation of Permits [326 IAC 2-1.1-9(5)]

Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this permit 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.

B.5 Permit Term and Renewal [326 IAC 2-6.1-7(a)][326 IAC 2-1.1-9.5]

This permit is issued for a fixed term of five (5) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions of this permit do not affect the expiration date.

The Permittee shall apply for an operation permit renewal at least ninety (90) days prior to the expiration date. If a timely and sufficient permit application for a renewal has been made, this permit shall not expire and all terms and conditions shall continue in effect until the renewal permit has been issued or denied.

B.6 Modification to Permit [326 IAC 2]

Notwithstanding the Section B condition entitled "Minor Source Operating Permit", all requirements and conditions of this construction permit shall remain in effect unless modified in a manner consistent with procedures established for modifications of construction permits pursuant to 326 IAC 2 (Permit Review Rules).

B.7 Minor Source Operating Permit [326 IAC 2-6.1]

This document shall also become a minor source operating permit pursuant to 326 IAC 2-6.1 when, prior to start of operation, the following requirements are met:

- (a) The attached Affidavit of Construction shall be submitted to the Office of Air Quality (OAQ), Permit Administration & Development Section.
 - (1) If the Affidavit of Construction verifies that the facilities covered in this Construction Permit were constructed as proposed in the application, then the facilities may begin operating on the date the Affidavit of Construction is postmarked or hand delivered to IDEM.
 - (2) If actual construction of the emission units differs from the construction proposed in the application, the source may not begin operation until the permit has been revised pursuant to 326 IAC 2-6.1-6 and an Operation Permit Validation Letter is issued.

- (b) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
- (c) Upon receipt of the Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section, the Permittee shall attach it to this document.
- (d) The operation permit will be subject to annual operating permit fees pursuant to 326 IAC 2-1.1-7(Fees).

B.8 Annual Notification [326 IAC 2-6.1-5(a)(5)]

- (a) Annual notification shall be submitted to the Office of Air Quality stating whether or not the source is in operation and in compliance with the terms and conditions contained in this permit.
- (b) Noncompliance with any condition must be specifically identified. If there are any permit conditions or requirements for which the source is not in compliance at any time during the year, the Permittee must provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be, achieved. The notification must be signed by an authorized individual.
- (c) The annual notice shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted in the format attached no later than March 1 of each year to:

Compliance Branch, Office of Air Quality
Indiana Department of Environmental Management
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251
- (d) The notification 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.

B.9 Preventive Maintenance Plan [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) within ninety (90) days after issuance of this permit, including the following information on each emissions unit:
 - (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
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

The PMP extension notification does not require the certification by an “authorized individual” as defined by 326 IAC 2-1.1-1(1).

- (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 PMP’s 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 PMP whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions or potential to emit. The PMP does not require the certification by an “authorized individual” as defined by 326 IAC 2-1.1-1(1).
- (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 that unit.

B.10 Permit Revision [326 IAC 2-5.1-3(e)(3)] [326 IAC 2-6.1-6]

- (a) Permit revisions are governed by the requirements of 326 IAC 2-6.1-6.
- (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
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

Any such application shall be certified by an “authorized individual” as defined by 326 IAC 2-1.1-1.
- (c) The Permittee shall notify the OAQ within thirty (30) calendar days of implementing a notice-only change. [326 IAC 2-6.1-6(d)]
- (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.

**B.11 Inspection and Entry [326 IAC 2-5.1-3(e)(4)(B)] [326 IAC 2-6.1-5(a)(4)][IC 13-14-2-2]
[IC 13-30-3-1]**

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee’s right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

- (a) Enter upon the Permittee's premises where a permitted source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
- (b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under this title or the conditions of this permit or any operating permit revisions;
- (c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any processes, emissions units (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit or any operating permit revisions;
- (d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and
- (e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.12 Transfer of Ownership or Operation [326 IAC 2-6.1-6(d)(3)]

Pursuant to [326 IAC 2-6.1-6(d)(3)] :

- (a) In the event that ownership of this source is changed, the Permittee shall notify IDEM, OAQ, Permits Branch, within thirty (30) days of the change.
- (b) The written notification shall be sufficient to transfer the permit to the new owner by an notice-only change pursuant to 326 IAC 2-6.1-6(d)(3).
- (c) IDEM, OAQ, shall issue a revised permit.

The notification which shall be submitted by the Permittee does require the certification by the "authorized individual" as defined by 326 IAC 2-1.1-1.

B.13 Annual Fee Payment [326 IAC 2-1.1-7]

- (a) The Permittee shall pay annual fees to IDEM, OAQ within thirty (30) calendar days of receipt of a billing.
- (b) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, I/M & Billing Section), to determine the appropriate permit fee.

SECTION C

SOURCE OPERATION CONDITIONS

Entire Source

C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) pounds per hour [326 IAC 6-3-2

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Permit Revocation [326 IAC 2-1.1-9]

Pursuant to 326 IAC 2-1.1-9 (Revocation of Permits), this permit to construct and operate may be revoked for any of the following causes:

- (a) Violation of any conditions of this permit.
- (b) Failure to disclose all the relevant facts, or misrepresentation in obtaining this permit.
- (c) Changes in regulatory requirements that mandate either a temporary or permanent reduction of discharge of contaminants. However, the amendment of appropriate sections of this permit shall not require revocation of this permit.
- (d) Noncompliance with orders issued pursuant to 326 IAC 1-5 (Episode Alert Levels) to reduce emissions during an air pollution episode.
- (e) For any cause which establishes in the judgment of IDEM, the fact that continuance of this permit is not consistent with purposes of this article.

C.3 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.4 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).

C.5 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

The Permittee shall comply with the applicable requirements of 326 IAC 14-10, 326 IAC 18, and 40 CFR 61.140.

Testing Requirements

C.6 Performance Testing [326 IAC 3-6]

- (a) Compliance testing on new emissions 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 permit, 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, OAQ.

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

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

no later than thirty-five (35) days prior to the intended test date.

- (b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual date.
- (c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by the IDEM, OAQ, if the source submits to IDEM, OAQ, a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

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 by issuing an order under 326 IAC 2-1.1-11. 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

C.8 Compliance Monitoring [326 IAC 2-1.1-11]

Compliance with applicable requirements shall be documented as required by this permit. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. All monitoring and record keeping requirements not already legally required shall be implemented when operation begins.

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.

Record Keeping and Reporting Requirements

C.10 Malfunctions Report [326 IAC 16-2]

Pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunction):

- (a) A record of all malfunctions, including startups or shutdowns of any facility or emission control equipment, which result in violations of applicable air pollution control regulations or applicable emission limitations shall be kept and retained for a period of three (3) years and shall be made available to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) or appointed representative upon request.
- (b) When a malfunction of any facility or emission control equipment occurs which lasts more than one (1) hour, said condition shall be reported to OAQ, using the Malfunction Report Forms (2 pages). Notification shall be made by telephone or facsimile, as soon as practicable, but in no event later than four (4) daytime business hours after the beginning of said occurrence.
- (c) Failure to report a malfunction of any emission control equipment shall constitute a violation of 326 IAC 1-6, and any other applicable rules. Information of the scope and expected duration of the malfunction shall be provided, including the items specified in 326 IAC 1-6-2(a)(1) through (6).
- (d) Malfunction is defined as any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. [326 IAC 1-2-39]

C.11 General Record Keeping Requirements [326 IAC 2-6.1-5]

- (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 when operation begins.

C.12 General Reporting Requirements [326 IAC 2-1.1-11] [326 IAC 2-6.1-2] [IC 13-14-1-13]

- (a) 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
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

- (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, any quarterly or semi-annual report required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. The report(s) does(do) not require the certification by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).
- (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)]:

The pharmaceutical manufacturing operation consisting of:

- (1) One (1) mixing and formulation process, located in Buildings A, C, and D, mixing pharmaceuticals in batches at a worst case maximum rate of 440 pounds per hour;
- (2) One (1) ancillary product filtration process, located in Buildings A, C, and D, removing suspended solids from the pharmaceuticals in preparation for packaging;
- (3) One (1) vial or syringe preparation process, located in Buildings A, C, and D, decontaminating vials and syringes in preparation for filling with the pharmaceuticals produced;
- (4) One (1) ancillary product filling process, located in Buildings A, C, and D, dispensing finished pharmaceuticals into vials or syringes in preparation for capping;
- (5) One (1) ancillary capping process, located in Buildings A, C, and D, applying a cap in each vial or syringe in preparation for final packaging; and
- (6) One (1) final packing process, packaging the capped vials and syringes in containers in preparation for shipping, located in Building B.

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

Emission Limitations and Standards

D.1.1 Preventive Maintenance Plan [326 IAC 1-6-3]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this equipment and any control devices.

SECTION D.2

FACILITY OPERATION CONDITIONS

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

- (b) Two (2) 1.075 MMBtu/hr natural gas tangential fired boilers, identified as BR03 and BR04 located in Building A.
- (c) Two (2) 7.328 MMBtu/hr natural gas tangential fired boilers, identified as BR01 and BR02, located in Building A.
- (d) Two (2) 3.000 MMBtu/hr natural gas tangential fired boilers, identified as BR06 and BR07, located in Building C.
- (e) One (1) 14.7 MMBtu/hr natural gas tangential fired boiler, identified as BR05, located in Building C.
- (f) One (1) 0.45 MMBtu/hr natural gas tangential fired boiler, identified as BR09, located in Building F.
- (g) One (1) 5.59 MMBtu/hr No. 2 fuel oil fired internal combustion emergency generator, identified as GN02, providing service to Buildings A and C.
- (h) One (1) 0.56 MMBtu/hr natural gas fired emergency generator, identified as GN01, providing service to Building B.
- (i) One (1) 6.43 MMBtu/hr No. 2 fuel oil fired emergency generator, identified as GN05, providing service to Building D.
- (j) Three (3) natural gas-fired boilers (identified as BR11, BR12, and BR13), each with a maximum heat input capacity of 14.7 MMBtu per hour. These units were installed in 2004.

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

Emission Limitations and Standards

D.2.1 Particulate [326 IAC 6-2-4]

Pursuant to 326 IAC 6-2-4(a) (Particulate Emission Limitations for Sources of Indirect Heating), the particulate emissions from the natural gas-fired boilers, all constructed after September 21, 1983, shall not exceed the pounds per million British thermal units heat input limit as shown in the table below:

Emission Unit ID (Boilers)	Total Source Max Heat Input Capacity (MMBtu/hr)	Particulate Emission Limit (lb/MMBtu)
BR01 through BR07, and BR09	38.0	0.42
BR11 through BR13	82.1	0.35

These limitations are based on the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Where Pt = Pounds of particulate matter emitted per million Btu (lb per MMBtu) heat input.
Q = Total source maximum operating capacity rating in million Btu per hour heat input.

D.2.2 Preventive Maintenance Plan [326 IAC 1-6-3]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this facility and its control device.

Record Keeping and Reporting Requirements [326 IAC 2-5.1-3(e)(2)] [326 IAC 2-6.1-5(a)(2)]

D.2.3 Notification Requirements for Boilers BR11, BR12, and BR13 [40 CFR 60.48c(a), 326 IAC 12]

The Permittee shall submit to the Office of Air Quality, a notification regarding Boilers BR11, BR12, BR13, and BR05. Said notification shall:

- (a) include:
 - (1) the date of construction or reconstruction, the date of anticipated startup, and the date of actual startup, as provided in 40 CFR 60.7; and
 - (2) the design heat input capacity of the boilers and identification of the fuels combusted in the boilers; and
- (b) be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, IN 46204-2251

D.2.4 Record Keeping Requirements [40 CFR 60.48c(g) and (i), 326 IAC 12]

- (a) The Permittee shall maintain daily fuel records for the four (4) natural gas fired boilers (identified as BR05, BR11, BR12, and BR13).

Said records shall be maintained for a minimum period of two years following the date the information is recorded.
- (b) To document compliance with Condition D.2.2, the Permittee shall maintain records of any additional inspection prescribed by the Preventive Maintenance Plan.
- (c) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH**

**MINOR SOURCE OPERATING PERMIT
ANNUAL NOTIFICATION**

This form should be used to comply with the notification requirements under 326 IAC 2-6.1-5(a)(5).

Company Name:	Baxter Pharmaceutical Solutions LLC
Address:	927 South Curry Pike
City:	Bloomington, Indiana 47403
Phone #:	812-333-0887
MSOP #:	105-16441-00040

I hereby certify that Baxter Pharmaceutical Solutions LLC is still in operation.
 no longer in operation.

I hereby certify that Baxter Pharmaceutical Solutions LLC is in compliance with the requirements of MSOP 105-16441-00040.
 not in compliance with the requirements of MSOP 105-16441-00040.

Authorized Individual (typed):
Title:
Signature:
Date:

If there are any conditions or requirements for which the source is not in compliance, provide a narrative description of how the source did or will achieve compliance and the date compliance was, or will be achieved.

Noncompliance:

MALFUNCTION REPORT

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
FAX NUMBER - 317 233-5967**

This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

THIS FACILITY MEETS THE APPLICABILITY REQUIREMENTS BECAUSE IT HAS POTENTIAL TO EMIT 25 TONS/YEAR PARTICULATE MATTER ?_____, 25 TONS/YEAR SULFUR DIOXIDE ?_____, 25 TONS/YEAR NITROGEN OXIDES?_____, 25 TONS/YEAR VOC ?_____, 25 TONS/YEAR HYDROGEN SULFIDE ?_____, 25 TONS/YEAR TOTAL REDUCED SULFUR ?_____, 25 TONS/YEAR REDUCED SULFUR COMPOUNDS ?_____, 25 TONS/YEAR FLUORIDES ?_____, 100TONS/YEAR CARBON MONOXIDE ?_____, 10 TONS/YEAR ANY SINGLE HAZARDOUS AIR POLLUTANT ?_____, 25 TONS/YEAR ANY COMBINATION HAZARDOUS AIR POLLUTANT ?_____, 1 TON/YEAR LEAD OR LEAD COMPOUNDS MEASURED AS ELEMENTAL LEAD ?_____, OR IS A SOURCE LISTED UNDER 326 IAC 2-5.1-3(2) ?_____. EMISSIONS FROM MALFUNCTIONING CONTROL EQUIPMENT OR PROCESS EQUIPMENT CAUSED EMISSIONS IN EXCESS OF APPLICABLE LIMITATION _____.

THIS MALFUNCTION RESULTED IN A VIOLATION OF: 326 IAC _____ OR, PERMIT CONDITION # _____ AND/OR PERMIT LIMIT OF _____

THIS INCIDENT MEETS THE DEFINITION OF 'MALFUNCTION' AS LISTED ON REVERSE SIDE ? Y N

THIS MALFUNCTION IS OR WILL BE LONGER THAN THE ONE (1) HOUR REPORTING REQUIREMENT ? Y N

COMPANY: _____ PHONE NO. () _____
LOCATION: (CITY AND COUNTY) _____
PERMIT NO. _____ AFS PLANT ID: _____ AFS POINT ID: _____ INSP: _____
CONTROL/PROCESS DEVICE WHICH MALFUNCTIONED AND REASON: _____

DATE/TIME MALFUNCTION STARTED: ____/____/20____ _____ AM / PM

ESTIMATED HOURS OF OPERATION WITH MALFUNCTION CONDITION: _____

DATE/TIME CONTROL EQUIPMENT BACK-IN SERVICE ____/____/20____ _____ AM/PM

TYPE OF POLLUTANTS EMITTED: TSP, PM-10, SO2, VOC, OTHER: _____

ESTIMATED AMOUNT OF POLLUTANT EMITTED DURING MALFUNCTION: _____

MEASURES TAKEN TO MINIMIZE EMISSIONS: _____

REASONS WHY FACILITY CANNOT BE SHUTDOWN DURING REPAIRS:

CONTINUED OPERATION REQUIRED TO PROVIDE ESSENTIAL* SERVICES: _____
CONTINUED OPERATION NECESSARY TO PREVENT INJURY TO PERSONS: _____
CONTINUED OPERATION NECESSARY TO PREVENT SEVERE DAMAGE TO EQUIPMENT: _____
INTERIM CONTROL MEASURES: (IF APPLICABLE) _____

MALFUNCTION REPORTED BY: _____ TITLE: _____
(SIGNATURE IF FAXED)

MALFUNCTION RECORDED BY: _____ DATE: _____ TIME: _____

Please note - This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

326 IAC 1-6-1 Applicability of rule

Sec. 1. This rule applies to the owner or operator of any facility required to obtain a permit under 326 IAC 2-5.1 or 326 IAC 2-6.1.

326 IAC 1-2-39 "Malfunction" definition

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner.

***Essential services** are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

If this item is checked on the front, please explain rationale:
