



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

TO: Interested Parties / Applicant

DATE: May 27, 2009

RE: Pfizer Inc / 167 - 27914 - 00013

FROM: Matthew Stuckey, Branch 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, Suite N 501E, 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.dot12/3/07



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

Mr. David L. Rader
Pfizer, Inc.
100 Pfizer Drive
Terre Haute, In 47802

May 27, 2009

Re: First Registration Notice-Only Change
No. R167-27914-00013

Dear Mr. Rader:

Pfizer, Inc. was issued a Registration No. R167-19525-00013 on June 30, 2005 for a stationary batch pharmaceutical manufacturing operation located at 100 Pfizer Drive, Terre Haute, Indiana. On May 11, 2009, the Office of Air Quality (OAQ) received an application from the source requesting that the registration be revised to remove all requirements related to local air pollution control agencies. Local agencies no longer have effective authority to implement state and federal requirements for IDEM. Therefore, IDEM has removed all references to local agencies from the registration. IDEM has determined that this change to the registration will be processed as a notice-only change pursuant to 326 IAC 2-5.5-6. Additionally, IDEM, OAQ has decided to revise the Registration in a new format.

The revised registration specifies that all reports, notices, applications, and any other required submittals shall be submitted to IDEM. The Permittee should note that the local agency could have its own requirements beyond the state and federal requirements contained in the registration. Please contact the local agency for further information.

The source shall continue to operate according to 326 IAC 2-5.5. Please find enclosed the revised registration. A copy of the registration is available on the Internet at: <http://www.in.gov/ai/appfiles/idem-caats/>. For additional information about air permits and how the public and interested parties can participate, refer to the IDEM's Guide for Citizen Participation and Permit Guide on the Internet at: www.idem.in.gov

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 Swarna Prabha, at (800) 451-6027, press 0 and ask for Swarna Prabha or extension 4-5376, or dial (317) 234-5376.

Sincerely,

Iryn Calilung, Section Chief
Permits Branch
Office of Air Quality

IC /sp

Attachment: Revised Registration

cc: File - Vigo County
Vigo County Health Department
Compliance and Enforcement Branch
Billing, Licensing and Training Section



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

**REGISTRATION
OFFICE OF AIR QUALITY**

**Pfizer, Inc.
100 Pfizer Drive
Terre Haute, Indiana 47802**

Pursuant to 326 IAC 2-5.1 (Construction of New Sources: Registrations) and 326 IAC 2-5.5 (Registrations), (herein known as the Registrant) is hereby authorized to construct and operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this registration.

Registration No. 167-19525-00013	
Original signed by: George M. Needham, Director Vigo County Air Pollution Control	Issuance Date: June 30, 2005

First Registration Notice-Only Change No. 167-27914-00013	
Issued by:  Iryn Calilung, Section Chief Permits Branch Office of Air Quality	Issuance Date: May 27, 2009

SECTION A

SOURCE SUMMARY

This registration 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 and A.2 is descriptive information and does not constitute enforceable conditions. However, the Registrant 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 Registrant to obtain additional permits pursuant to 326 IAC 2.

A.1 General Information

The Registrant owns and operates a stationary batch pharmaceutical manufacturing operation.

Source Address:	100 Pfizer Drive, Terre Haute, Indiana 47802
Mailing Address:	100 Pfizer Drive, Terre Haute, Indiana 47802
General Source Phone Number:	(812) 299- 2121
SIC Code:	2834
County Location:	Vigo County (Pearson Township)
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Registration

A.2 Emission Units and Pollution Control Equipment Summary

This stationary source consists of the following emission units and pollution control devices:

- (a) One (1) pharmaceutical manufacturing operation, identified as Bldg 1247, for sterile products. This facility includes process tanks and vessels, sterilization filters, a crystallizer, a centrifuge, product dryers, mills and packaging equipment. Emissions exhaust to stacks 3 and 4. Bldg 1247 was constructed in 1981.
- (b) Other activities or categories not previously identified: Pharmaceutical production processes in Buildings 1238, 1243, 1244, 1247 and 1250, including all storage tanks associated with the listed buildings.

Pfizer, Inc. was issued a Title V Operating Permit on June 28, 2004. The January 20, 2005 application transfers the majority of emission units to Danisco Sweeteners (167-20471-00138, effective 12:01 AM July 1, 2005). Pfizer's remaining emission units qualify the source as a Registration. Therefore the source may operate according to 326 IAC 2-5.5.

Intentionally left blank.... continued on next page....

SECTION B

GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-1.1-1]

Terms in this registration 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.2 Effective Date of Registration [IC 13-15-5-3]

Pursuant to IC 13-15-5-3, this registration is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

B.3 Registration Revocation [326 IAC 2-1.1-9]

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

- (a) Violation of any conditions of this registration.
- (b) Failure to disclose all the relevant facts, or misrepresentation in obtaining this registration.
- (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 registration shall not require revocation of this registration.
- (d) For any cause which establishes in the judgment of the fact that continuance of this registration is not consistent with purposes of this article.

B.4 Prior Permits Superseded [326 IAC 2-1.1-9.5]

- (a) All terms and conditions of permits established prior to Registration No. 167-19525-00013 and issued pursuant to permitting programs approved into the state implementation plan have been either:
 - (1) incorporated as originally stated,
 - (2) revised, or
 - (3) deleted.
- (b) All previous registrations and permits are superseded by this registration.

B.5 Annual Notification [326 IAC 2-5.1-2(f)(3)] [326 IAC 2-5.5-4(a)(3)]

Pursuant to 326 IAC 2-5.1-2(f)(3) and 326 IAC 2-5.5-4(a)(3):

- (a) An annual notification shall be submitted by an authorized individual 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 registration.
- (b) The annual notice shall be submitted in the format attached no later than March 1 of each year to:

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

- (c) 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.6 Source Modification Requirement [326 IAC 2-5.5-6(a)]

Pursuant to 326 IAC 2-5.5-6(a), an application or notification shall be submitted in accordance with 326 IAC 2 to the Office of Air Quality (OAQ) if the source proposes to construct new emission units, modify existing emission units, or otherwise modify the source.

B.7 Registrations [326 IAC 2-5.1-2(i)]

Pursuant to 326 IAC 2-5.1-2(i), this registration does not limit the source's potential to emit.

Intentionally left blank.... continued on next page....

SECTION C

SOURCE OPERATION CONDITIONS

Entire Source

Emission Limitations and Standards [326 IAC 2-5.1-2(g)] [326 IAC 2-5.5-4(b)]

C.1 Opacity [326 IAC 5-1]

Pfizer Inc is located outside of the coordinates that limits the opacity to thirty percent (30%). Therefore 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:

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 registration:

- (a) Opacity shall not exceed an average of thirty 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.2 Fugitive Dust Emissions [326 IAC 6-4]

The Registrant 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).

Intentionally left blank.... continued on next page....

SECTION D.1

OPERATION CONDITIONS

Facility Description [326 IAC 2-5.1-2(f)(2)] [326 IAC 2-5.5-4(a)(2)]:

- (a) One (1) pharmaceutical manufacturing operation, identified as Bldg 1247, for sterile products. This facility includes process tanks and vessels, sterilization filters, a crystallizer, a centrifuge, product dryers, mills and packaging equipment. Emissions exhaust to stacks 3 and 4. Bldg 1247 was constructed in 1981.
- (b) Other activities or categories not previously identified: Pharmaceutical production processes in Buildings 1238, 1243, 1244, 1247 and 1250, including all storage tanks associated with the listed buildings.

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

Intentionally left blank.... continued on next page....

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

**REGISTRATION
ANNUAL NOTIFICATION**

This form should be used to comply with the notification requirements under 326 IAC 2-5.1-2(f)(3) and 326 IAC 2-5.5-4(a)(3).

Company Name:	Pfizer, Inc.
Address:	100 Pfizer Drive, Terre Haute, IN 47802
City:	Terre Haute, IN 47802
Phone Number:	(812) 299-2121
Registration No.:	167-19525-00013

I hereby certify that Pfizer, Inc. is :	<input type="checkbox"/> still in operation.
	<input type="checkbox"/> no longer in operation.
I hereby certify that Pfizer, Inc. is :	<input type="checkbox"/> in compliance with the requirements of Registration No. 167-19525-00013.
	<input type="checkbox"/> not in compliance with the requirements of Registration No. 167-19525-00013.

Authorized Individual (typed):
Title:
Signature:
Phone Number:
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:



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

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

SENT VIA U.S. MAIL: CONFIRMED DELIVERY AND SIGNATURE REQUESTED

TO: David L Rader
Pfizer Inc
PO Box 88
Terre Haute, IN 47802

DATE: May 27, 2009

FROM: Matt Stuckey, Branch Chief
Permits Branch
Office of Air Quality

SUBJECT: Final Decision
Registration - NOC - Local Agency Conditions
167 - 27914 - 00013

Enclosed is the final decision and supporting materials for the air permit application referenced above. Please note that this packet contains the original, signed, permit documents.

The final decision is being sent to you because our records indicate that you are the contact person for this application. However, if you are not the appropriate person within your company to receive this document, please forward it to the correct person.

A copy of the final decision and supporting materials has also been sent via standard mail to:
Anibal Carlo, Site Leader
OAQ Permits Branch Interested Parties List

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178, or toll-free at 1-800-451-6027 (ext. 3-0178), and ask to speak to the permit reviewer who prepared the permit. If you think you have received this document in error, please contact Joanne Smiddie-Brush of my staff at 1-800-451-6027 (ext 3-0185), or via e-mail at jbrush@idem.IN.gov.

Final Applicant Cover letter.dot 11/30/07

Mail Code 61-53

IDEM Staff	LPOGOST 5/27/2009 Pfizer Inc 167 - 27914 - 00013 (final)		AFFIX STAMP HERE IF USED AS CERTIFICATE OF MAILING
Name and address of Sender		Indiana Department of Environmental Management Office of Air Quality – Permits Branch 100 N. Senate Indianapolis, IN 46204	

TYPE OF MAIL:
CERTIFICATE OF MAILING ONLY

Line	Article Number	Name, Address, Street and Post Office Address	Postage	Handling Charges	Act. Value (If Registered)	Insured Value	Due Send if COD	R.R. Fee	S.D. Fee	S.H. Fee	Rest. Del. Fee
											Remarks
1		David L Rader Pfizer Inc PO Box 88 Terre Haute IN 47802 (Source CAATS) Via confirmed delivery									
2		Anibal Carlo Site Leader Pfizer Inc PO Box 88 Terre Haute IN 47808 (RO CAATS)									
3		Mr. Charles L. Berger Berger & Berger, Attorneys at Law 313 Main Street Evansville IN 47700 (Affected Party)									
4		Vigo County Board of Commissioners County Annex, 121 Oak Street Terre Haute IN 47807 (Local Official)									
5		Terre Haute City Council and Mayors Office 17 Harding Ave Terre Haute IN 47807 (Local Official)									
6		Vigo County Health Department 147 Oak Street Terre Haute IN 47807 (Health Department)									
7		J.P. Roehm PO Box 303 Clinton IN 47842 (Affected Party)									
8		George Needham Vigo County Air Pollution Control 103 South Third St. Terre Haute IN 47807 (Local Official)									
9											
10											
11											
12											
13											
14											
15											

Total number of pieces Listed by Sender	Total number of Pieces Received at Post Office	Postmaster, Per (Name of Receiving employee)	The full declaration of value is required on all domestic and international registered mail. The maximum indemnity payable for the reconstruction of nonnegotiable documents under Express Mail document reconstructing insurance is \$50,000 per piece subject to a limit of \$50,000 per occurrence. The maximum indemnity payable on Express mail merchandise insurance is \$500. The maximum indemnity payable is \$25,000 for registered mail, sent with optional postal insurance. See Domestic Mail Manual R900, S913, and S921 for limitations of coverage on insured and COD mail. See International Mail Manual for limitations of coverage on international mail. Special handling charges apply only to Standard Mail (A) and Standard Mail (B) parcels.
---	--	--	--