



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL  
HAMILTON COUNTY**

**CERTIFIED MAIL**

Street Address:

122 S. Front Street

Lazarus Gov. Center TELE: (614) 644-3020 FAX: (614) 644-2329

Mailing Address:

Lazarus Gov. Center  
P.O. Box 1049

**Application No: 14-05893**

**Fac ID: 1431074228**

**DATE: 12/29/2006**

Forest Pharmaceuticals, Inc.  
Greg Plant Manager  
3941 Brotherton Road  
Cincinnati, OH 45209

Enclosed please find an Ohio EPA Permit to Install which will allow you to install the described source(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, I urge you to read it carefully.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469.

You are hereby notified that this action of the Director is final and may be appealed to the Environmental Review Appeals Commission pursuant to Section 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. The appeal must be filed with the Commission within thirty (30) days after notice of the Director's action. The appeal must be accompanied by a filing fee of \$70.00 which the Commission, in its discretion, may reduce if by affidavit you demonstrate that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3) days of filing with the Commission. Ohio EPA requests that a copy of the appeal be served upon the Ohio Attorney General's Office, Environmental Enforcement Section. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission  
309 South Fourth Street, Room 222  
Columbus, OH 43215

Sincerely,

Michael W. Ahern, Manager  
Permit Issuance and Data Management Section  
Division of Air Pollution Control

CC: USEPA

HCDES



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**Permit To Install  
Terms and Conditions**

**Issue Date: 12/29/2006  
Effective Date: 12/29/2006**

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**FINAL PERMIT TO INSTALL 14-05893**

Application Number: 14-05893  
Facility ID: 1431074228  
Permit Fee: **\$400**  
Name of Facility: Forest Pharmaceuticals, Inc.  
Person to Contact: Greg Plant Manager  
Address: 3941 Brotherton Road  
Cincinnati, OH 45209

Location of proposed air contaminant source(s) [emissions unit(s)]:  
**3941 Brotherton Road  
Cincinnati, Ohio**

Description of proposed emissions unit(s):  
**Initial PTI to permit an existing Fluid Bed Granulator.**

The above named entity is hereby granted a Permit to Install for the above described emissions unit(s) pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this permit does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the above described emissions unit(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans and specifications, the above described emissions unit(s) of pollutants will be granted the necessary permits to operate (air) or NPDES permits as applicable.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

Forest Pharmaceuticals, Inc.  
PTI Application: 14-05893  
Issued: 12/29/2006

Facility ID: 1431074228

## Part I - GENERAL TERMS AND CONDITIONS

### A. Permit to Install General Terms and Conditions

#### 1. Compliance Requirements

The emissions unit(s) identified in this Permit to Install shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

#### 2. Reporting Requirements

The permittee shall submit required reports in the following manner:

- a. Reports of any required monitoring and/or recordkeeping information shall be submitted to the appropriate Ohio EPA District Office or local air agency.
- b. Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and recordkeeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the appropriate Ohio EPA District Office or local air agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted (i.e., postmarked) quarterly by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

#### 3. Records Retention Requirements

Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to, all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

#### 4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon

**Forest Pharmaceuticals, Inc.**  
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the premises of this source at any reasonable time for purposes of making inspections, conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

**5. Scheduled Maintenance/Malfunction Reporting**

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction of any emissions units or any associated air pollution control system(s) shall be reported to the appropriate Ohio EPA District Office or local air agency in accordance with paragraph (B) of OAC rule 3745-15-06. Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emissions unit(s) that is (are) served by such control system(s).

**6. Permit Transfers**

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The appropriate Ohio EPA District Office or local air agency must be notified in writing of any transfer of this permit.

**7. Air Pollution Nuisance**

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

**8. Termination of Permit to Install**

This Permit to Install shall terminate within eighteen months of the effective date of the Permit to Install if the owner or operator has not undertaken a continuing program of installation or modification or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation or modification. This deadline may be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the party shows good cause for any such extension.

**9. Construction of New Sources(s)**

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The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

If the construction of the proposed emissions unit(s) has already begun or has been completed prior to the date the Director of the Environmental Protection Agency approves the permit application and plans, the approval does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the approved plans. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of the Permit to Install does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Approval of the plans in any case is not to be construed as an approval of the facility as constructed and/or completed. Moreover, issuance of the Permit to Install is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities cannot meet the requirements of this permit or cannot meet applicable standards.

#### **10. Public Disclosure**

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

#### **11. Applicability**

This Permit To Install is applicable only to the emissions unit(s) identified in the Permit To Install. Separate Permit To Install for the installation or modification of any other emissions unit(s) are required for any emissions unit for which a Permit To Install is required.

#### **12. Best Available Technology**

As specified in OAC Rule 3745-31-05, all new sources must employ Best Available Technology (BAT). Compliance with the terms and conditions of this permit will fulfill this requirement.

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**13. Source Operation and Operating Permit Requirements After Completion of Construction**

This facility is permitted to operate each source described by this Permit to Install for a period of up to one year from the date the source commenced operation. This permission to operate is granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within ninety (90) days after commencing operation of the emissions unit(s) covered by this permit.

**14. Construction Compliance Certification**

The applicant shall provide Ohio EPA with a written certification (see enclosed form) that the facility has been constructed in accordance with the Permit to Install application and the terms and conditions of the Permit to Install. The certification shall be provided to Ohio EPA upon completion of construction but prior to startup of the source.

**15. Fees**

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable Permit to Install fees within 30 days after the issuance of this Permit to Install.

**B. Permit to Install Summary of Allowable Emissions**

The following information summarizes the total allowable emissions, by pollutant, based on the individual allowable emissions of each air contaminant source identified in this permit.

SUMMARY (for informational purposes only)  
 TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	24.82
PE/PM10	0.08

**PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)****A. Applicable Emissions Limitations and/or Control Requirements**

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

**Operations, Property, and/or Equipment - (P001) - Fluid Bed Granulator**

Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
OAC rule 3745-31-05(A)(3)	Organic Compound (OC) emissions shall not exceed 14.7 pounds per hour (lbs/hour) and 24.82 tons per year (TPY).  Particulate Emissions (PE) and emissions of Particulate Matter 10 microns or less in diameter (PM10) shall not exceed 0.03 lb/hour and 0.08 TPY.  See terms and conditions A.2.c and B.1.
OAC rule 3745-17-07(A)(1)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05 (A)(3).
OAC rule 3745-17-11	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05 (A)(3).
OAC rule 3745-21-07(G)(2)	This rule is not applicable. See term and condition B.2.

**2. Additional Terms and Conditions**

- 2.a Compliance with OAC rule 3745-31-05(A)(3) is necessary due to the fact that the emission unit was installed prior to August 3, 2006, as stated in ORC 3704.03(T)(4).
- 2.b Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of HEPA filtration, an operating hours limitation, and compliance with the visible and mass emissions limitations.
- 2.c Visible particulate emissions from this emissions unit shall not exceed 10 percent opacity, as a six minute average.

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**B. Operational Restrictions**

1. The actual OC usage in this emissions unit shall not exceed an annual limit of 24.82 tons per year.
2. The use of photochemically reactive material as defined in OAC rule 3745-21-01(C)(5) is prohibited.

**C. Monitoring and/or Recordkeeping Requirements**

1. The permittee shall collect and record the following information each day for each batch using organic liquids:
  - a. Date the batch was produced.
  - b. The total OC usage (amount of organic liquids used) in pounds per batch.
  - c. Production run time for each batch
  - c. The hourly OC usage rate (b/c).

These records shall be summarized at the end of each calendar year to determine the annual OC emissions.

2. The permittee shall collect and record the following information each month:
  - a. the company identification of each liquid organic material employed in this emissions unit; and
  - b. a record of each liquid organic material employed in this emissions unit indicating, whether or not the liquid organic material is photochemically reactive as identified in OAC rule 3745-21-01(C)(5).

3. The permit to install for emissions unit P001 was evaluated based on the actual materials and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied to this emissions unit for each toxic pollutant, using data from the permit to install application, and modeling was performed for the toxic pollutant(s) emitted at over a ton per year using the SCREEN3 model or other Ohio EPA approved model. The predicted 1-hour

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maximum ground-level concentration result(s) from the use of the SCREEN3 (or other approved) model, was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: isopropanol

TLV (mg/m<sup>3</sup>): 491.53

Maximum Hourly Emission Rate (lbs/hr): 14.7

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m<sup>3</sup>): 6385

MAGLC (ug/m<sup>3</sup>): 11703

Physical changes to or changes in the method of operation of the emission units after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used or the use of new materials, that would result in the emission of a compound or chemical with a lower Threshold Limit Value (TLV) than the lowest TLV previously modeled, as documented in the most current version of the American Conference of Governmental Industrial Hygienists' (ACGIH's) handbook entitled "TLVs and BEIs" ("Threshold Limit Values for Chemical Substances and Physical Agents, Biological Exposure Indices");
- b. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be

Emissions Unit ID: **P001**

required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) meet(s) the definition of a "modification" under other provisions of the rule, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will still satisfy the "Air Toxic Policy":

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of the evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

#### **D. Reporting Requirements**

1. The permittee shall submit deviation (excursion) reports that identify all exceedances of the following:
  - a. Each hour during which the OC emissions exceeded 14.7 lbs/hour, and the actual OC emissions for each such hour.
2. The deviation reports shall be submitted in accordance with the General Terms and Conditions of this permit.
3. The annual OC use in this emissions unit for each calendar year shall be reported to the Hamilton County Department of Environmental Services by January 31 of each year and shall cover the annual use for the previous calendar year.
4. The permittee shall notify the Hamilton County Department of Environmental Services in writing identifying each day during which any photochemically reactive material (as defined in OAC rule 3745-21-01(C)(5)) was employed in this emissions unit. This report shall identify the cause for the use of the photochemically reactive material(s) and the estimated total quantity of organic compound emissions emitted each such day. This report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after

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the exceedance occurs.

## E. Testing Requirements

1. Compliance with the emissions limitations specified in Section A.1 shall be determined by the following methods:

- a. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a 6-minute average.

Applicable Compliance Method:

Compliance with the visible particulate emissions limitation shall be demonstrated by the methods outlined in 40 CFR Part 60, Appendix A, Method 9.

- b. Emissions limitations:

0.03 lb PE/PM10/hour and 0.08 ton per year of PE/PM10.

Applicable Compliance Method:

Compliance shall be determined utilizing the total material maximum throughput (286.6 lbs/batch) divided by the run time per cycle (3.25 hours) times 1 minus the minimum overall particulate control efficiency of 99.97%, as provided in permit to install application 14-05893 received on November 9, 2006. The annual emissions rate shall be determined by multiplying the hourly emissions rate by the actual production run time for this emissions unit, not including turn around time between batches, divided by 2000 lbs/ton. All PE is assumed to be PM10 emissions.

- c. Emissions limitations:

14.7 lbs of OC/hour and 24.82 tons per year.

Applicable Compliance Method:

Compliance shall be demonstrated by utilizing the recorded OC usage (lbs/batch) divided by the running time of the batch in hours, excluding turn around time. The annual emission rate shall be determined by summing the annual OC use.

2. Compliance with the operation restriction in term and condition B.1 shall be demonstrated by the record keeping in term and condition C.1.

**Forest Pharmaceuticals, Inc.**

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**Facility ID: 1431074228**

**Emissions Unit ID: P001**

3. Compliance with the operation restriction in term and condition B.2 shall be demonstrated by the record keeping in term and condition C.2.

**F. Miscellaneous Requirements**

None