Ohio Environmental Protection Agency
John R. Kasich, Governor
Mary Taylor, Lt. Governor
Scott J. Nally, Director

Certified Mail

4/25/2012

JAMES MURPHY
BOEHRINGER INGELHEIM ROXANE INC
PO BOX 16532
COLUMBUS, OH 43216

No	TOXIC REVIEW
No	PSD
No	SYNTHETIC MINOR TO AVOID MAJOR NSR
No	CEMS
No	MACT/GACT
No	NSPS
No	NESHAPS
No	NETTING
No	MAJOR NON-ATTAINMENT
No	MODELING SUBMITTED
No	SYNTHETIC MINOR TO AVOID TITLE V
No	FEDERALLY ENFORCABLE PTIO (FEPTIO)
No	SYNTHETIC MINOR TO AVOID MAJOR GHG

RE: FINALAIR POLLUTION PERMIT-TO-INSTALL AND OPERATE
Facility ID: 0125040886
Permit Number: P0082756
Permit Type: Renewal
County: Franklin

Dear Permit Holder:

Enclosed please find a final Air Pollution Permit-to-Install and Operate (PTIO) which will allow you to install, modify, and/or operate the described emissions unit(s) in the manner indicated in the permit. Because this permit contains conditions and restrictions, please read it very carefully. Please complete a survey at www.epa.ohio.gov/dapc/permitsurvey.aspx and give us feedback on your permitting experience. We value your opinion.

The issuance of this PTI is a final action of the Director 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, made payable to “Ohio Treasurer Josh Mandel," 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

If you have any questions, please contact Ohio EPA DAPC, Central District Office at (614)728-3778or the Office of Compliance Assistance and Pollution Prevention at (614) 644-3469. This permit can be accessed electronically on the DAPCWeb page,www.epa.ohio.gov/dapc, by clicking the "Issued Air Pollution Control Permits" link.

Sincerely,

Michael W. Ahern

Michael W. Ahern, Manager
Permit Issuance and Data Management Section, DAPC

Cc: Ohio EPA-CDO

Ohio | Environmental Protection Agency

FINAL

Division of Air Pollution Control
Permit-to-Install and Operate
for
BOEHRINGER INGELHEIM ROXANE INC

Facility ID:	0125040886
Permit Number:	P0082756
Permit Type:	Renewal
Issued:	4/25/2012
Effective:	4/25/2012
Expiration:	4/25/2022

Ohio Environmental Protection Agency

Division of Air Pollution Control
Permit-to-Install and Operate
for
BOEHRINGER INGELHEIM ROXANE INC

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Authorization

Facility ID: 0125040886
Application Number(s): A0013099
Permit Number: P0082756
Permit Description: PTIO Renewal permit for Pharmaceutical Manufacturing and Packaging Operation-Granulation
Permit Type: Renewal
Permit Fee: $0.00
Issue Date: 4/25/2012
Effective Date: 4/25/2012
Expiration Date: 4/25/2022
Permit Evaluation Report (PER) Annual Date: Oct 1 - Sept 30, Due Nov 15

This document constitutes issuance to:

BOEHRINGER INGELHEIM ROXANE INC
330 OAK ST
COLUMBUS, OH 43216

of a Permit-to-Install and Operate for the emissions unit(s) identified on the following page.

Ohio EPA District Office or local air agency responsible for processing and administering your permit:

Ohio EPA DAPC, Central District Office
50 West Town Street, 6th Floor
P.O. Box 1049
Columbus, OH 43216-1049
(614)728-3778

The above named entity is hereby granted this Permit-to-Install and Operate for the air contaminant source(s) (emissions unit(s))listed in this section 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 described emissions unit(s) will operate in compliance with applicable State and federal laws and regulations.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Scott J. Nally
Director

Authorization (continued)

Permit Number: P0082756
Permit Description: PTIO Renewal permit for Pharmaceutical Manufacturing and Packaging Operation-Granulation

Permits for the following Emissions Unit(s) or groups of Emissions Units are in this document as indicated below:

Emissions Unit ID:	**P002**
Company Equipment ID:	Granulation
Superseded Permit Number:	01-08002
General Permit Category and Type:	Not Applicable

A. Standard Terms and Conditions

1. What does this permit-to-install and operate ("PTIO") allow me to do?

This permit allows you to install and operate the emissions unit(s) identified in this PTIO. You must install and operate the unit(s) in accordance with the application you submitted and all the terms and conditions contained in this PTIO, including emission limits and those terms that ensure compliance with the emission limits (for example, operating, recordkeeping and monitoring requirements).

2. Who is responsible for complying with this permit?

The person identified on the "Authorization" page, above, is responsible for complying with this permit until the permit is revoked, terminated, or transferred. "Person" means a person, firm, corporation, association, or partnership. The words "you," "your," or "permittee" refer to the "person" identified on the "Authorization" page above.

The permit applies only to the emissions unit(s) identified in the permit. If you install or modify any other equipment that requires an air permit, you must apply for an additional PTIO(s) for these sources.

3. What records must I keep under this permit?

You must keep all records required by this permit, including monitoring data, test results, strip-chart recordings, calibration data, maintenance records, and any other record required by this permit for five years from the date the record was created. You can keep these records electronically, provided they can be made available to Ohio EPA during an inspection at the facility. Failure to make requested records available to Ohio EPA upon request is a violation of this permit requirement.

4. What are my permit fees and when do I pay them?

There are two fees associated with permitted air contaminant sources in Ohio:

PTIO fee. This one-time fee is based on a fee schedule in accordance with Ohio Revised Code (ORC) section 3745.11, or based on a time and materials charge for permit application review and permit processing if required by the Director.

You will be sent an invoice for this fee after you receive this PTIO and payment is due within 30 days of the invoice date. You are required to pay the fee for this PTIO even if you do not install or modify your operations as authorized by this permit.

Annual emissions fee. Ohio EPA will assess a separate fee based on the total annual emissions from your facility. You self-report your emissions in accordance with Ohio Administrative Code (OAC) Chapter 3745-78. This fee assessed is based on a fee schedule in ORC section 3745.11 and funds Ohio EPA's permit compliance oversight activities. Unless otherwise specified, facilities subject to one or more synthetic minor restrictions must use Ohio EPA's "Air Services" to submit annual emissions associated with this permit requirement.Ohio EPA will notify you when it is time to report your emissions and to pay your annual emission fees.

5. When does my PTIO expire, and when do I need to submit my renewal application?

This permit expires on the date identified at the beginning of this permit document (see "Authorization" page above) and you must submit a renewal application to renew the permit. Ohio EPA will send a renewal notice to you approximately six months prior to the expiration date of this permit. However, it is

very important that you submit a complete renewal permit application (postmarked prior to expiration of this permit) even if you do not receive the renewal notice.

If a complete renewal application is submitted before the expiration date, Ohio EPA considers this a timely application for purposes of ORC section 119.06, and you are authorized to continue operating the emissions unit(s) covered by this permit beyond the expiration date of this permit until final action is takenby Ohio EPA on the renewal application.

6. What happens to this permit if my project is delayed or I do not install or modify my source?

This PTIO expires 18 months after the issue date identified on the "Authorization" page above unless otherwise specified if you have not (1) started constructing the new or modified emission sources identified in this permit, or (2) entered into a binding contract to undertake such construction. This deadline can be extended by up to 12 months, provided you apply to Ohio EPA for this extension within a reasonable time before the 18-month period has ended and you can show good cause for any such extension.

7. What reports must I submit under this permit?

An annual permit evaluation report (PER) is required in addition to any malfunction reporting required by OAC rule 3745-15-06 or other specific rule-based reporting requirement identified in this permit. Your PER due date is identified in the Authorization section of this permit.

8. If I am required to obtain a Title V operating permit in the future, what happens to the operating provisions and PER obligations under this permit?

If you are required to obtain a Title V permit under OAC Chapter 3745-77 in the future, the permit-to-operate portion of this permit will be superseded by the issued Title V permit. From the effective date of the Title V permit forward, this PTIO will effectively become a PTI (permit-to-install) in accordance with OAC rule 3745-31-02(B). The following terms and conditions will no longer be applicable after issuance of the Title V permit: Section B, Term 1.b) and Section C, for each emissions unit, Term a)(2).

The PER requirements in this permit remain effective until the date the Title V permit is issued and is effective, and cease to apply after the effective date of the Title V permit. The final PER obligation will cover operations up to the effective date of the Title V permit and must be submitted on or before the submission deadline identified in this permit on the last day prior to the effective date of the Title V permit.

9. What are my obligations when I perform scheduled maintenance on air pollution control equipment?

You must perform scheduled maintenance of air pollution control equipment in accordance with OAC rule 3745-15-06(A). If scheduled maintenance requires shutting down or bypassing any air pollution control equipment, you must also shut down the emissions unit(s) served by the air pollution control equipment during maintenance, unless the conditions of OAC rule 3745-15-06(A)(3) are met. Any emissions that exceed permitted amount(s) under this permit (unless specifically exempted by rule) must be reported as deviations in the annual permit evaluation report (PER), including nonexempt excess emissions that occur during approved scheduled maintenance.

10. Do I have to report malfunctions of emissions units or air pollution control equipment? If so, how must I report?

If you have a reportable malfunction of any emissions unit(s) or any associated air pollution control system, you must report this to the Ohio EPA DAPC, Central District Office in accordance with OAC rule 3745-15-06(B). Malfunctions that must be reported are those that result in emissions that exceed permitted emission levels. It is your responsibility to evaluate control equipment breakdowns and operational upsets to determine if a reportable malfunction has occurred.

If you have a malfunction, but determine that it is not a reportable malfunction under OAC rule 3745-15-06(B), it is recommended that you maintain records associated with control equipment breakdown or process upsets. Although it is not a requirement of this permit, Ohio EPA recommends that you maintain records for non-reportable malfunctions.

11. Can Ohio EPA or my local air agency inspect the facility where the emission unit(s) is/are located?

Yes. Under Ohio law, the Director or his authorized representative may inspect the facility, conduct tests, examine records or reports to determine compliance with air pollution laws and regulations and the terms and conditions of this permit. You must provide, within a reasonable time, any information Ohio EPA requests either verbally or in writing.

12. What happens if one or more emissions units operated under this permit is/are shut down permanently?

Ohio EPA can terminate the permit terms associated with any permanently shut down emissions unit. "Shut down" means the emissions unit has been physically removed from service or has been altered in such a way that it can no longer operate without a subsequent "modification" or "installation" as defined in OAC Chapter 3745-31.

You should notify Ohio EPA of any emissions unit that is permanently shut down by submitting[1] a certification that identifies the date on which the emissions unit was permanently shut down. The certification must be submitted by an authorized official from the facility. You cannot continue to operate an emissions unit once the certification has been submitted to Ohio EPA by the authorized official.

You must comply with all recordkeeping and reporting for any permanently shut down emissions unit in accordance with the provisions of the permit, regulations or laws that were enforceable during the period of operation, such as the requirement to submit a PER, air fee emission report, or malfunction report. You must also keep all records relating to any permanently shutdown emissions unit, generated while the emissions unit was in operation, for at least five years from the date the record was generated.

Again, you cannot resume operation of any emissions unit certified by the authorized official as being permanently shut down without first applying for and obtaining a permit pursuant to OAC Chapter 3745-31.

[1]Permittees that use Ohio EPA's "Air Services" can mark the affected emissions unit(s) as "permanently shutdown" in the facility profile along with the date the emissions unit(s) was permanently removed and/or disabled. Submitting the facility profile update will constitute notifying of the permanent shutdown of the affected emissions unit(s).

13. Can I transfer this permit to a new owner or operator?

You can transfer this permit to a new owner or operator. If you transfer the permit, you must follow the procedures in OAC Chapter 3745-31, including notifying Ohio EPA or the local air agency of the change in ownership or operator. Any transferee of this permit must assume the responsibilities of the transferor permit holder.

14. Does compliance with this permit constitute compliance with OAC rule 3745-15-07, "air pollution nuisance"?

This permit and OAC rule 3745-15-07 prohibit operation of the air contaminant source(s) regulated under this permit in a manner that causes a nuisance. Ohio EPA can require additional controls or modification of the requirements of this permit through enforcement orders or judicial enforcement action if, upon investigation, Ohio EPA determines existing operations are causing a nuisance.

15. What happens if a portion of this permit is determined to be invalid?

If a portion of this permit is determined to be invalid, the remainder of the terms and conditions remain valid and enforceable. The exception is where the enforceability of terms and conditions are dependent on the term or condition that was declared invalid.

B. Facility-Wide Terms and Conditions

1. This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

   a) For the purpose of a permit-to-install document, the facility-wide terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

      (1) None.

   b) For the purpose of a permit-to-operate document, the facility-wide terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

      (1) None.

C. Emissions Unit Terms and Conditions

1. P002, Granulation

Operations, Property and/or Equipment Description:

Pharmaceutical Manufacturing and Packaging Operation

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. None.

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. None.

b) Applicable Emissions Limitations and/or Control Requirements

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

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3) (PTI No. 08002, issued 3/15/2000)	Emissions shall not exceed: 0.10 pound per hour particulate emissions (PE) and 0.10 ton per year. 10 pounds per hour volatile organic compounds (VOC) and 5.50 tons per year. There shall be no visible emissions from this emissions unit. The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-07(A)(1) and OAC rule 3745-17-11(B)(1). See b)(2)(a.

b.	OAC rule 3745-17-07(A)(1)	The emissions limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
c.	OAC rule 3745-17-11(B)(1)	The emissions limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

(2) Additional Terms and Conditions

a. The emissions from the emissions unit shall vent to a baghouse, pleated filter, and HEPA filter (with composite control efficiency of 99.99%). These control devices are considered an inherent physical limitation since they are used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and the DEA require total accountability for the pharmaceuticals manufactured by Roxane Laboratories. Due to this inherent physical limitation, monitoring for visible emissions is unnecessary.

c) Operational Restrictions

(1) The permittee shall not employ an alcohol with an organic compound content greater than 98%, by weight.

d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall maintain daily records of the following information:

a. the number of gallons of alcohol employed;

b. the density of the alcohol, in pounds per gallon;

c. the percent of organic compounds, by weight;

d. the total number of hours the emissions unit was in operation;

e. the total uncontrolled organic compound emissions, in pounds per day; and

f. the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).

(2) The permittee shall maintain daily records that document any time when the baghouse, pleated filter and/or HEPA filter were not in service while the emissions unit was in operation.

e) Reporting Requirements

(1) The permittee shall submit an annual Permit Evaluation Report (PER) to the Ohio EPA, Central District Office, Division of Air Pollution Control by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting

period of no more than twelve-months for each air contaminant source identified in this permit. It is recommended that the PER is submitted electronically through the Ohio EPA's "e-Business Center: Air Services" although PERs can be submitted via U.S. Postal Service or can be hand delivered.

(2) The permittee shall notify the Director of the Ohio EPA, Central District Office, Division of Air Pollution Control, in writing of any daily record showing that the baghouse, pleated filter and/or HEPA filter were not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Director of the Ohio EPA, Central District Office, Division of Air Pollution Control, within 30 days after the event occurs.

f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitation:

No visible emission

Applicable Compliance Method:

If required, compliance shall be determined through visible emissions observations performed in accordance with the procedures specified in OAC rule 3745-17-03(B)(4).

b. Emission Limitation:

Particulate emissions shall not exceed 0.1 pound per hour and 0.1 ton per year

Applicable Compliance Method:

Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 793 pounds per hour by the non-recovered product loss of 0.25 (determined by company mass balance) and 0.0001 (control factor). This value represents the potential-to-emit.

c. Emission Limitation:

10.0 lbs/hr organic compounds (OC) and 5.50 TPY.

Applicable Compliance Method:

Compliance shall be determined by the monitoring and recordkeeping established in Section d)(1).

g) Miscellaneous Requirements

(1) None.