#### OPERATING PERMIT

In accordance with provisions of the Air Pollution Control Act, the act of January 8, 1960, P.L. 2119, <u>as amended</u>, and after due consideration of an application received under Chapter 127 of the Rules and Regulations of the Department of Environmental Protection, the Department hereby issues this permit for the operation of the air contamination source(s) described below:

Permit No.	OP-46-0027	Source(s)	Facility VOC & NOx RACT
Owner	Ortho-McNeil Pharmaceutical	Air	
Address	Welsh & McKean Roads	Cleaning	
	Spring House, PA 19477	Device	
Attention	Mike Esposito	Location	Welsh & McKean Roads
	Environmental Engineer		Lower Gwynedd Township
			Montgomery County

This permit is subject to the following conditions:

- That the source(s) and any associated air cleaning devices are to be:
  - a. operated in such a manner as not to cause air pollution;
  - b. in compliance with the specifications and conditions of any plan approval issued;
  - operated and maintained in a manner consistent with good operating and maintenance practices.
- 2. This permit is valid only for the specific equipment, location and owner named above.

#### (SEE ADDITIONAL CONDITIONS ATTACHED)

Failure to comply with the conditions placed on this permit is a violation of Section 127.444. Violation of this or any other provision of Article III of the Rules and Regulations of the Department of Environmental Protection will result in suspension or revocation of this permit and/or prosecution under Section 9 of the Air Pollution Control Act.

Issued

06/04/1998

Francine Carlini

Expires 06/03/2003

Regional Manager

Air Quality

cc: Central Office, Harrisburg

Division of Permits, RCSOB

Administration

SEFO

RACT Binder

Re (JCD)248-4

## OPERATING PERMIT CONDITIONS PERMIT NO. OP-46-0027 ORTHO-MCNEIL PHARMACEUTICAL

### CONDITIONS (continued):

- This operating permit incorporates Reasonably Available Control Technology (RACT)
  determinations as required by Title I provisions of the Clean Air Act Amendments, and 25 Pa.
  Code Sections 129.91 through 129.95 for the following sources:
  - i. Boilers #1 and #2 (Kewanee, 21 MMBtu/hr each)
  - ii. PANCREASE Process with Catalytic Oxidizer
  - iii. Emergency Generators #1, #2 (Caterpillar, 750 KW, 130 KW), & #3 (Onan, 100 KW)
  - iv. Fire Water Pump
  - v. Waste Consolidation Area
  - vi. Print Shop
  - vii. Gasoline tank(010, Miscellaneous 200-gallon)
  - viii. Tanks for storing solvent (007, 008)
  - ix. Tanks for storing diesel fuel or No. 2 fuel oil (010A, 011A, 012A, 014A, 015A, 016A)
  - x. Laboratory Hoods
- This operating permit supersedes and incorporates all previously issued Operating Permits bearing the number(s) 46-302-127 and 46-313-073.
- 5. The expiration date shown on the operating permit is for state purposes. For Federal enforcement purposes the RACT provisions of the operating permit shall remain in effect as part of the State Implementation Plan (SIP) until replaced pursuant to 40 CFR 51 and approved by the U.S. Environmental Protection Agency (EPA).
- For purposes of RACT, the volatile organic compounds (VOC) emissions from the PANCREASE
  process with catalytic oxidizer shall not exceed 50 tons per year calculated on a 12-month rolling
  basis.
- 7. For purposes of RACT, the emissions of VOC from <u>each</u> de-minimus source category shall not exceed 3 pounds per hour, 15 pounds per day or 2.7 tons per year a 12 month rolling sum. The following sources listed in Condition 3 are de-minimus source categories:
  - i. boilers
  - ii. emergency generators
  - iii. waste consolidation area
  - iv. print shop
  - v. storage tanks
  - vi. laboratory hoods

# OPERATING PERMIT CONDITIONS PERMIT NO. OP-46-0027 ORTHO-MCNEIL PHARMACEUTICAL

### CONDITIONS (continued):

9.

- The catalytic oxidizer shall achieve and maintain a minimum of 85% VOC destruction/removal efficiency.
  - NOx RACT for boilers 1 and 2, identified in condition 3.i. herein, are the annual adjustments or tune-up in accordance with 25 Pa. Code Section 129.93 (b)(2.3,4 and 5) of Chapter 129 of Article III of the Rules and Regulations of the Department of Environmental Protection. At a minimum this includes:
    - Inspection, adjustment, cleaning or replacement of fuel-burning equipment, including the burners and moving parts necessary for proper operation as specified by the manufacturer.
    - Inspection of the flame pattern or characteristics and adjustments necessary to minimize total emissions of NOx and, to the extent practicable minimize emissions of CO.
    - iii. Inspection of the air-to-fuel ratio control system and adjustments necessary to ensure proper calibration and operation as specified by the manufacturer.
  - b. Record each adjustment conducted under the procedures mentioned in the above paragraph (9.a.) in a permanently bound log book or other method approved by the Department. This record shall contain at a minimum, the following information:
    - i. The date of the tuning procedure.
    - The name of the service company and technicians.
    - iii. The final operating rate or load.
    - iv. The final CO and NOx emission rates.
    - v. The final excess oxygen rate.
    - vi. Other information required by the applicable operating permit.

# OPERATING PERMIT CONDONS PERMIT NO. OP-46-0027 ORTHO-MCNEIL PHARMACEUTICAL

### CONDITIONS (continued):

- c. All oil, gas and combination oil/gas fired units subject to 25 Pa. Code Section 129.93 (b)(2) shall maintain records including certification from the fuel supplier of the type of fuel and for each shipment of distillate oils number 1 or 2, a certification that the fuel comply with ASTM D396-78 "Standards Specifications for Fuel Oils".
- d. The annual adjustment shall be made in accordance with the EPA document "Combustion Efficiency Optimization Manual for Operators of Oil and Gas-fired Boilers," September 1983 (EPA-340/1-83-023) or equivalent procedures approved in writing by the Department.
- Pursuant to the presumptive RACT provisions of 25 Pa. Code Section 129.93 (c)(5) of Chapter 129 of Article III of the Rule and Regulations of the Department of Environmental Protection, the emergency generators and fire water pump identified in condition 3.iii. and 3.iv. respectively, herein shall be maintained and operated in accordance with manufacturer's specifications. The sources shall also be operated and maintained in accordance with good air pollution control practices. Additionally, the emergency generators and fire water pump shall not be (individually) operated in excess of 500 hours in any 12 consecutive calendar month period.
- Pursuant to the presumptive RACT provisions of 25 Pa. Code Section 129.93 (c)(4) of Chapter 129 of Article III of the Rule and Regulations of the Department of Environmental Protection, the catalytic oxidizer identified in condition 3.ii, herein shall be maintained and operated in accordance with manufacturer's specifications. The source shall also be operated and maintained in accordance with good air pollution control practices.
- 12. Ortho-McNeil shall maintain records in accordance with the following minimum recordkeeping requirements. At a minimum, this shall include:
  - Records shall provide sufficient data and calculations to clearly demonstrate that the requirements of Condition No. 6, 7, 8, 9 and 10 are met. This includes:
    - i. Boiler(s), Oxidizer, and Emergency generator(s) fuel usage
    - ii. Emission factors used to determine emissions and
    - iii. Other parameters as may be required by the Department
  - b. Data or information required to determine compliance with Condition No. 6 and 7 shall be recorded and maintained in a time frame consistent with the averaging period of the requirements.

# OPERATING PERMIT CONDITIONS PERMIT NO. OP-46-0027 ORTHO-MCNEIL PHARMACEUTICAL

### CONDITIONS (continued):

- Records shall be retained for at least five years and be made available to the Department upon request.
- Boilers #1 & #2 shall be fired with natural gas with the secondary fuel being No. 2 fuel oil to which there has been no reclaimed or waste oil or other waste materials added. Additionally, the sulfur content of the No. 2 fuel oil fired in these boilers shall not, at any time, exceed 0.3% (by weight)
- Ortho-McNeil shall, upon Department request, provide fuel analysis or fuel samples of the fuels used in the aforementioned boilers.
- 15. The catalytic incinerator covered under operating permit number 46-313-073 must be equipped with an alarm that sounds when the inlet temperature to the heat exchanger reaches 300 F or the inlet temperature to the burner reaches 800 F or the outlet temperature from the catalyst bed reaches 1400 F. Any of these situations results in the process being shutdown.
- 16. The company shall install a monitor to continuously monitor the solvent vapor concentrations in the exhaust air from the coaters and dryers.
- The company shall not impose conditions upon or otherwise restrict the Department's access to the aforementioned source(s) and/or any associated air cleaning device(s) and shall allow the Department to have access at any time to said source(s) and associated air cleaning device(s) with such measuring and recording equipment, including equipment recording visual observations, as the Department deems necessary and proper for performing its duties and for the effective enforcement of the Air Pollution Control Act.

#### 18: General Conditions:

If at any time the Department has cause to believe that air contaminant emissions from the aforementioned source(s) may be in excess of the limitations specified in, or established pursuant to, any applicable rule or regulation contained in Article III of the Rule and Regulations of the Department of Environmental Protection, the company shall be required to conduct whatever tests are deemed necessary by the Department to determine the actual emission rate(s). Such testing shall be conducted in accordance with the provisions of Chapter 139 of the Rule and Regulations of the Department of Environmental Protection, where applicable, and in accordance with any restrictions or limitations established by the Department at such time as it notifies the company that testing is required.

# OPERATING PERMIT CONDITION PERMIT NO. OP-46-0027 ORTHO-MCNEIL PHARMACEUTICAL

## CONDITIONS (continued):

- The company, within one hour of occurrence, shall notify the Department, at 610-832-6242, of any malfunction of the source(s) or associated air cleaning device(s) which results in, or may possibly by resulting in, the emission of air contaminants in excess of the limitations specified in, or established pursuant to, any applicable rule or regulation contained in Article III of the Rules and Regulations of the Department of Environmental Protection. A written report shall be submitted to the Department within two working days following the incident describing the malfunctions and corrective action taken.
- If at any time the permittee causes, permits or allows any modification (as that term is defined in Chapter 121 of Title 25, the Rule and Regulations of the Department of Environmental Protection) of the aforementioned air contamination source(s), the operation and use of which is authorized by this permit, or causes, permits or allows any modifications, malfunction or removal of any air pollution control device required as a condition of this permit, then and in that event, this permit shall be suspended, and the permittee shall not thereafter continue to operate or use said air contamination source(s).
- This operating permit is valid for a limited period of time and may be renewed before its expiration. Requests for an operating permit renewal must be in writing and must be accompanied by the appropriate permit application processing and annual permit administration fees as specified in Section 127.703 of the Rules and Regulations of the Department of Environmental Protection. These fees shall be paid in the form of a check payable to the "Commonwealth of Pennsylvania-Clean Air Fund." The request should be made using the appropriate application form and must be received by the Department along with a completed Air Pollution Control Act Compliance Review form no later than 60 days prior to the expiration date of this permit.

All necessary forms can be obtained from the Department upon request.

20. Any notification required as a result of any condition herein should be directed to:

Regional Air Quality Manager Lee Park, 555 North Lane, Suite 6010 Conshohocken, PA 19428