



DEPARTMENT OF NATURAL RESOURCES

MISSOURI AIR CONSERVATION COMMISSION

PERMIT TO CONSTRUCT

Under the authority of RSMo 643 and the Federal Clean Air Act the applicant is authorized to construct the air contaminant source(s) described below, in accordance with the laws, rules and conditions as set forth herein.

Permit Number: 122009-011 Project Number: 2009-07-020

Parent Company: Teva Pharmaceuticals USA

Parent Company Address: 650 Cathill Road, Sellersville, PA 18960

Installation Name: Teva Pharmaceuticals USA

Installation Address: 5000 Snyder Drive, Mexico, MO 65265

Location Information: Audrain County, S4, T50N, R8W

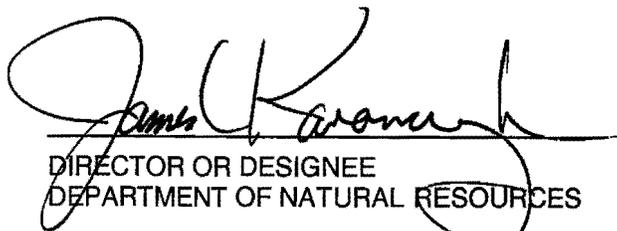
Application for Authority to Construct was made for:
Increase in the allowed annual number of Amoxicillan batches from 1,250 batches per year to 2,100 batches per year. This review was conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*.

Standard Conditions (on reverse) are applicable to this permit.

Standard Conditions (on reverse) and Special Conditions are applicable to this permit.

DEC 17 2009

EFFECTIVE DATE


DIRECTOR OR DESIGNEE
DEPARTMENT OF NATURAL RESOURCES

STANDARD CONDITIONS:

Permission to construct may be revoked if you fail to begin construction or modification within two years from the effective date of this permit. Permittee should notify the Air Pollution Control Program if construction or modification is not started within two years after the effective date of this permit, or if construction or modification is suspended for one year or more.

You will be in violation of 10 CSR 10-6.060 if you fail to adhere to the specifications and conditions listed in your application, this permit and the project review. In the event that there is a discrepancy between the permit application and this permit, the conditions of this permit shall take precedence. Specifically, all air contaminant control devices shall be operated and maintained as specified in the application, associated plans and specifications.

You must notify the departments' Air Pollution Control Program of the anticipated date of start up of this (these) air contaminant source(s). The information must be made available not more than 60 days but at least 30 days in advance of this date. Also, you must notify the Department of Natural Resources Regional office responsible for the area within which you are located within 15 days after the actual start up of this (these) air contaminant source(s).

A copy of this permit and permit review shall be kept at the installation address and shall be made available to Department of Natural Resources' personnel upon request.

You may appeal this permit or any of the listed special conditions to the Administrative Hearing Commission (AHC), P.O. Box 1557, Jefferson City, MO 65102, as provided in RSMo 643.075.6 and 621.250.3. If you choose to appeal, you must file a petition with the AHC within 30 days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed. If it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the AHC.

If you choose not to appeal, this certificate, the project review and your application and associated correspondence constitutes your permit to construct. The permit allows you to construct and operate your air contaminant source(s), but in no way relieves you of your obligation to comply with all applicable provisions of the Missouri Air Conservation Law, regulations of the Missouri Department of Natural Resources and other applicable federal, state and local laws and ordinances.

The Air Pollution Control Program invites your questions regarding this air pollution permit. Please contact the Construction Permit Unit at (573) 751-4817. If you prefer to write, please address your correspondence to the Missouri Department of Natural Resources, Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102-0176, attention: Construction Permit Unit.

REVIEW OF APPLICATION FOR AUTHORITY TO CONSTRUCT AND OPERATE
SECTION (5) REVIEW

Project Number: 2009-07-020
Installation ID Number: 007-0040
Permit Number:

Teva Pharmaceuticals USA
5000 Snyder Drive
Mexico, MO 65265

Complete: August 4, 2009

Parent Company:
Teva Pharmaceuticals USA
650 Cathill Road
Sellersville, PA 18960

Audrain County, S4, T50N, R8W

REVIEW SUMMARY

- Teva Pharmaceuticals USA has applied for authority to increase the allowed annual number of Amoxicillan batches from 1,250 batches per year to 2,100 batches per year.
- Hazardous Air Pollutant (HAP) emissions are expected from the proposed equipment. The main HAP of concern from this process is methylene chloride. Other HAPs include triethylamine.
- Subpart Kb of the New Source Performance Standards (NSPS), *Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced after July 23, 1984*, applies to storage tanks identified as T-008 and T-010.
- The Maximum Achievable Control Technology (MACT) standard, 40 CFR Part 63, Subpart GGG, *National Emission Standards for Pharmaceutical Production* applies to the facility. Subpart H, *National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks*, and Subpart I, *National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks*, apply to the facility.
- A carbon adsorption unit (APC-18) is being used to control the methylene chloride emissions from the equipment used to make amoxicillin. Special conditions pertaining to the carbon adsorption unit can be found in Permit No. 092002-004.
- This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of all pollutants are below de minimis levels.

- This installation is located in Audrain County, an attainment area for all criteria air pollutants.
- This installation is on the List of Named Installations [10 CSR 10-6.020(3)(B), Table 2, Item 20 “Chemical Process Plant”].
- Ambient air quality modeling was not performed since potential emissions of the application are below de minimis levels
- Emissions testing is not required for the equipment.
- A revision to your Part 70 Operating Permit application is required for this installation within 1 year of equipment startup.
- Approval of this permit is recommended without special conditions.

INSTALLATION DESCRIPTION

TEVA Pharmaceutical USA (Teva) produces several pharmaceutical products (bulk antibiotic preparations) and intermediates (needed to manufacture the final antibiotic products) at its plant in Mexico, Missouri. Teva uses a variety of chemicals including solvents classified as volatile organic compounds (VOCs) and HAPs in a number of pharmaceutical manufacturing processes to produce its final and intermediate products. These processes typically consist of chemical synthesis steps, followed by product separation and drying. The installation was initially constructed in 1989. The existing installation is a major source of VOC emissions. A Part 70 Operating Permit (OP2008-021) was issued in April of 2008. The Operating Permit is currently under review for an administrative amendment.

The following permits have been issued to Teva Pharmaceuticals USA from the Air Pollution Control Program.

Table1: Previously Issued Construction Permits

Permit Number	Description
0989-004	Construction of a pharmaceutical production facility
1292-012	Increase Dane salt production and alter boiler operation
0395-002	Install solvent recovery (distillation) systems, operational changes
0797-032	Cephalosporin G expansion (2 reactors, 2 receivers, 2 holding tanks)
0597-013	Install two new dual fuel boilers
0198-024	Install bis-trimethylsilylurea manufacturing process
0198-034	Install amoxicillin trihydrate manufacturing process
1298-010	Install Cefaclor manufacturing process within existing equipment
0399-010	Install Cephalexin recovery equipment
102001-011	Modification of the Cephalexin process to increase production
092002-014	Modification to the existing Amoxicillin manufacturing process for increased production
022003-014	Modification to existing equipment to recover Cephalexin Monohydrate USP (Bulk) from the mother liquors (ML)
082003-002	Installation of a regenerative thermal oxidizer

PROJECT DESCRIPTION

TEVA Pharmaceuticals USA (Teva) has applied for authority to modify the existing Amoxicillin manufacturing process to allow for increased production from 1,250 batches per year to 2,100 batches per year. The Amoxicillin process was permitted for 1,500 batches per year in Permit No. 092002-014. In Project No. 2006-05-048, changes in the method used to produce Amoxicillin decreased the annual number of batches to 1,250, but increased the batch size from 490 kilograms to 588 kilograms. Teva is now proposing to increase production by decreasing the lag time between finishing a batch and starting the subsequent one within the initial set of reactors operated in the Amoxicillin pharmaceutical manufacturing process unit (PMPU). The requested increase in Amoxicillin production does not involve any additional process equipment or physical modifications of the existing equipment.

EMISSIONS/CONTROLS EVALUATION

The emission factors and control efficiencies used in this analysis were based on revised calculations submitted by Teva on September 29, 2009. A mass balance approach was used based on a maximum production rate of 2,100 batches per year. The carbon adsorption unit used to control the emissions from this process has a control efficiency of 95%. Special conditions for the control device can be found in Permit No. 092002-014. (Note that even though methylene chloride is considered a HAP, it is not considered a VOC.)

Potential emissions of the application are based on the production of 2,100 batches which is the maximum amount of batches that can be produced while operating continuously (8760 hours per year). Existing potential emissions were obtained from the previous permit (Permit No. 082003-002). Existing actual emissions were obtained from the Teva's 2008 Emission Inventory Questionnaire (EIQ) submittal. The following table provides an emissions summary for this project.

Table 2: Emissions Summary (tons per year)

Pollutant	Regulatory De Minimis Levels	Existing Potential Emissions	Existing Actual Emissions (2008 EIQ)	Potential Emissions of the Application	New Installation Conditioned Potential
PM ₁₀	15.0	>100	0.33	N/A	N/A
SO _x	40.0	>100	0.02	N/A	N/A
NO _x	40.0	>100	4.06	N/A	N/A
VOC	40.0	>100	23.7	0.91	N/A
CO	100.0	>100	0.51	N/A	N/A
HAPs	10.0/25.0	N/D*	8.46	10.24	N/A
Methylene chloride	10.0	N/D	4.52	9.32	N/A
Methanol	10.0	N/D	2.43	N/A	N/A
Toluene	10.0	N/D	1.07	N/A	N/A
Triethylamine	10.0	N/D	0.31	0.91	N/A

N/A = Not Applicable; N/D = Not Determined

*The existing total and individual HAPs were not calculated for the installation. Teva is already subject to a MACT and are required to submit a Part 70 due to their major source status for other pollutants.

PERMIT RULE APPLICABILITY

This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of all pollutants are below de minimis levels.

APPLICABLE REQUIREMENTS

Teva Pharmaceuticals USA shall comply with the following applicable requirements. The Missouri Air Conservation Laws and Regulations should be consulted for specific record keeping, monitoring, and reporting requirements. Compliance with these emission standards, based on information submitted in the application, has been verified at the time this application was approved. For a complete list of applicable requirements for your installation, please consult your operating permit.

GENERAL REQUIREMENTS

- *Submission of Emission Data, Emission Fees and Process Information*, 10 CSR 10-6.110
The emission fee is the amount established by the Missouri Air Conservation Commission annually under Missouri Air Law 643.079(1). Submission of an Emissions Inventory Questionnaire (EIQ) is required June 1 for the previous year's emissions.
- *Operating Permits*, 10 CSR 10-6.065
- *Restriction of Particulate Matter to the Ambient Air Beyond the Premises of Origin*, 10 CSR 10-6.170
- *Restriction of Emission of Visible Air Contaminants*, 10 CSR 10-6.220
- *Restriction of Emission of Odors*, 10 CSR 10-3.090

SPECIFIC REQUIREMENTS

- *New Source Performance Regulations*, 10 CSR 10-6.070 – *New Source Performance Standards (NSPS) for Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced after July 23, 1984*, 40 CFR Part 60, Subpart Kb
- *Maximum Achievable Control Technology (MACT) Regulations*, 10 CSR 10-6.075, *National Emission Standards for Pharmaceutical Production*, 40 CFR Part 63, Subpart GGG

- *Emission Standards for Hazardous Air Pollutants, 10 CSR 10-6.080 – National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 61, Subpart H, and NESHAPS for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks, Subpart I.*

STAFF RECOMMENDATION

On the basis of this review conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*, I recommend this permit be granted without special conditions.

Susan Heckenkamp
Environmental Engineer

Date

PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated July 8, 2009, received July 9, 2009, designating Teva Pharmaceuticals USA as the owner and operator of the installation.
- Corrections to the Application for Authority to Construct received via email, dated September 29, 2009.
- Northeast Regional Office Site Survey, dated August 13, 2009.

Mr. Don Reichert
Teva Pharmaceuticals USA
5000 Snyder Drive
Mexico, MO 65265

RE: New Source Review Permit - Project Number: 2009-07-020

Dear Mr. Reichert:

Enclosed with this letter is your permit to construct. Please study it carefully. Also, note the special conditions, if any, on the accompanying pages. The document entitled, "Review of Application for Authority to Construct," is part of the permit and should be kept with this permit in your files.

Operation in accordance with these conditions, your new source review permit application and with your revised operating permit is necessary for continued compliance.

The reverse side of your permit certificate has important information concerning standard permit conditions and your rights and obligations under the laws and regulations of the State of Missouri.

If you have any questions regarding this permit, please do not hesitate to contact Susan Heckenkamp, at the Departments' Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102 or at (573) 751-4817. Thank you for your attention to this matter.

Sincerely,

AIR POLLUTION CONTROL PROGRAM

Kendall B. Hale
New Source Review Unit Chief

KBH:shl

Enclosures

c: Northeast Regional Office
PAMS File: 2009-07-020

Permit Number: