



APR 18 2019

Mr. Jonathan Eckles
Environmental Manager
Mallinckrodt Pharmaceuticals
3600 N 2nd Street
St. Louis, MO 63147

RE: New Source Review Permit Amendment - Permit Number: 01-09-027PM-M
Project Number: 2018-12-014; Installation Number: 510-0017

Dear Mr. Eckles:

On December 10, 2018 the Air Pollution Control Program received your request to amend Permit Number 01-09-027PM, originally issued by the City of St. Louis. This permit has various existing amendments, as detailed in Table 1 below.

Table 1: Construction Permit 01-09-027 and amendments

Permit/Project Number	Date Issued	Issued by	Purpose
01-09-027	7/18/02	St. Louis City	Initial permit
01-09-027PM	5/29/03	St. Louis City	Permit correction
01-09-027PM	10/27/04	St. Louis City	Permit modification, effectively supersedes previous versions
01-09-027PM	11/2/04	St. Louis City	Permit amendment to add/modify/remove equipment
01-09-027PM	12/9/04	St. Louis City	Permit amendment to add equipment
01-09-027PM	1/18/05	St. Louis City	Permit amendment to add equipment
01-09-027PM	8/19/05	St. Louis City	Permit amendment to add equipment
01-09-027PM	11/21/05	St. Louis City	Permit amendment to add equipment
01-09-027PM	9/18/06	St. Louis City	Permit amendment to add equipment
01-09-027PM	10/31/08	St. Louis City	Permit clarification
01-09-027PM, 2006-10-009	11/13/08	MoDNR	Amendment to true up NOx emissions
01-09-027PM-L, 2017-03-041	3/24/17	MoDNR	Amendment to modify special conditions



This amendment will reflect the addition of a new centrifuge in Building 97, as detailed in Table 2. The unit is subject to the control device provisions of 40 CFR part 63, Subpart GGG, National Emission Standards for Pharmaceutical Production; therefore the control devices are federally enforceable and are included in the potential to emit calculations for this project. The controlled potential emissions of this new centrifuge are 0.1375 lb VOC per hour and 0.043 lbs methanol (HAP) per hour. Because the emissions from this new unit are being included in the current emission limitations established in Construction Permit 01-09-027, as amended, this project does not result in an emissions increase.

Table 2: New equipment added under this permit amendment

EP#	EP Description	Capacity	Installation Date	Mfr/Model	Control Device
2895	CF-4900 Comi Centrifuge	46 liter	2019	Comi Condor Horizontal Axis Peeler	Thermal Oxidizer followed by HCl Scrubber

This new equipment is subject to all emissions limitations, monitoring, recordkeeping, and reporting requirements established in the permits listed in Table 1; 40 CFR part 63 Subpart GGG, National Emission Standards for Pharmaceutical Production; and 10 CSR 10-5.350, Control of Emissions From Manufacture of Synthesized Pharmaceutical Products. The applicable portions of these regulations appear in the Part 70 Operating Permit. A Part 70 Operating Permit amendment is required to incorporate the new centrifuge.

A major modification is any physical change in or change in the method of operation of a major stationary source that would result in a significant emissions increase and a significant net emissions increase of a regulated NSR pollutant. Any changes at this installation must be evaluated according to the federal provisions for Prevention of Significant Deterioration and Non-Attainment New Source Review; as well as 10 CSR 10-6.060, Construction Permits Required. The emission caps established in the Table 1 permits do not supersede these requirements.

Mallinckrodt Pharmaceuticals is located in the City of St. Louis, a nonattainment area for the 2008 8-hour ozone standard and an attainment area for all other criteria pollutants. The installation is on the list of Named Installations, Item 20, Chemical Process Plants. As a named installation in the St. Louis nonattainment area, the installation's major source level, for construction permitting purposes, is 100 tons per year for all regulated NSR pollutants, including fugitive emissions.

If you were adversely affected by this permit decision, you may be entitled to pursue an appeal before the administrative hearing commission pursuant to Sections 621.250 and 643.075.6

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RSMo. To appeal, you must file a petition with the administrative hearing commission within thirty 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 administrative hearing commission, whose contact information is: Administrative Hearing Commission, United States Post Office Building, 131 West High Street, Third Floor, P.O. Box 1557, Jefferson City, Missouri 65102, phone: 573-751-2422, fax: 573-751-5018, website: www.ao.mo.gov/ahc.

If you have any questions regarding this amendment, please do not hesitate to contact Nicole Weidenbenner, P.E., at the department's 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
Permits Section Chief

KBH:nwj

Enclosures

c: St. Louis Regional Office
PAMS File: 2018-12-014

Permit No.	01-09-027PM-M
Project No.	2018-12-014

SPECIAL CONDITIONS:

The permittee is authorized to construct and operate subject to the following special conditions:

The special conditions listed in this permit were included based on the authority granted the Missouri Air Pollution Control Program by the Missouri Air Conservation Law (specifically 643.075) and by the Missouri Rules listed in Title 10, Division 10 of the Code of State Regulations (specifically 10 CSR 10-6.060). For specific details regarding conditions, see 10 CSR 10-6.060 paragraph (12)(A)10. "Conditions required by permitting authority."

1. This new equipment (EP # 2895, CF-4900 Comi Centrifuge) is subject to all emissions limitations, monitoring, recordkeeping, and reporting requirements established in Construction Permit 01-09-027, as amended.