



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

NOV 09 2017

Mr. Columba McGarvey
Site Director, AbbVie Ltd.
Road No.2, km. 58.0, Cruce Davila
P.O. Box 278
Barceloneta, PR 00617-0278

Re: Administrative Amendment to the Prevention of Significant Deterioration (PSD) Permit for the AbbVie Cogeneration Diesel Engine

Dear Mr. McGarvey:

The United States Environmental Protection Agency's Region 2 Office (EPA) received an October 11, 2017 submittal from the law firm of Toro, Colon, Mullet, Rivera & Sifre, P.S.C. on behalf of AbbVie Ltd., which owns and operates a pharmaceutical facility in Barceloneta, Puerto Rico. The submittal requests that EPA temporarily modify AbbVie's PSD permit to allow it to operate its Cogeneration Engine Unit (Cogen) up to 8,760 hours from its current limit of 8,297 hours per year. AbbVie stated that the recent events (Hurricanes Irma and Maria) have heavily impacted Puerto Rico's electric supply and that, due to the damage from these storms, AbbVie will not have a reliable source of back-up power from the local utility for some time to come. This lack of backup power is the reason why AbbVie seeks to operate its Cogen to provide the power for its pharmaceutical operations beyond the hours limited by the PSD permit.

AbbVie stated in its October 11, 2017 submittal, during an October 18, 2017 conference call, and in subsequent letters dated October 23 and 26, 2017, that AbbVie's request to increase the Cogen's operating hours from 8,297 to 8,760 will not result in any increase in the emissions from its 2009-2010 baseline actual emission levels. In fact, the projected actual emissions will be lower than the baseline actual emissions. AbbVie is also not requesting any change to the Cogen's short term emission limits for any pollutant. AbbVie asked that the Cogen's 20.2 MW (28,463 hp) capacity be limited to 17.1 MW (22,998 hp) (see October 26, 2017 letter) to ensure the lower projected actual emissions in the future. It also requested in its October 23, 2017 letter that the Cogen's No. 6 fuel oil's maximum sulfur limit be reduced from 2% to 1% and that the three 50 MMBtu/hr boilers be deleted from the PSD permit because they were dismantled and removed.

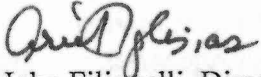
The facility, formerly owned by Abbott Pharmaceutical until 2013, was issued a PSD permit for its cogeneration engine and boilers in 1989, which was revised in 1992. It operates this cogeneration engine by combusting No. 6 fuel oil to produce electricity and steam. Based on the review of the information AbbVie provided, EPA has determined that AbbVie's requested permit modifications can be done administratively because the changes will not result in any increase in projected future emissions from the baseline actual emissions and will also not result in any changes to the Cogen's Best Available Control Technology (BACT) emission limits and will have no impact on air quality. These changes include: (1) increase in the Cogen's annual operating hours from 8,297 to 8,760; (2) decrease in the No. 6 fuel oil's maximum sulfur limit from 2% to 1%; (3) removal of three boilers; and (4) limiting its maximum power output to 17.1 MW (22,998 hp). The summary of the administrative changes to

AbbVie's PSD permit are provided in the Enclosure I. Today's administratively modified PSD permit can be found in Enclosure II. Although AbbVie requested a temporary modification to its PSD permit, the PSD regulation codified at 40 CFR §52.21 does not have any provision for a temporary modification to a PSD permit. Therefore, as we informed AbbVie, the revised permit conditions are not temporary. Since EPA's action is considered an administrative change to a PSD permit, it will not be subject to public review.

This determination is final Agency action under the Clean Air Act (the Act). Under Section 307 (b)(1) of the Act, judicial review of this final action is available only by the filing of a petition for review in the United States Court of Appeals for the appropriate circuit within 60 days from the date on which this final permit decision is published in the Federal Register. Under Section 307 (b)(2) of the Act, this final permit decision shall not be subject to later judicial review in civil or criminal proceedings for enforcement.

If you have any questions regarding this letter, please call Ms. Suilin W. Chan, Chief, Permitting Section, Air Programs Branch, at (212) 637-4019.

Sincerely,



for John Filippelli, Director
Clean Air and Sustainability Division

Enclosures

cc: Carlos E. Colon Franceschi, w/ Enclosures
Leimarys Delgado, PREQB w/ Enclosures
Luis Sierra Torres, PREQB w/ Enclosures

ENCLOSURE I

AbbVie, Ltd., Barceloneta, Puerto Rico Administrative Amendment to the PSD Permit- November 2017

Background:

AbbVie Ltd. (hereinafter, "AbbVie") currently operates a pharmaceutical products manufacturing facility located in the Municipality of Barceloneta, Puerto Rico. AbbVie manufactures pharmaceutical products of final dosage such as capsules, tablets and pellets. The facility was part of the manufacturing complex that was owned and operated by several subsidiaries of Abbott Laboratories ("Abbott") in Barceloneta, Puerto Rico (hereinafter "the former Abbott complex"). On January 1, 2013, Abbott completed a separation of its business into two separate and independent healthcare companies: (i) a corporation for diversified medical products, that retained the name of Abbott; and (ii) a new company for the research-based pharmaceutical business (that owns the pharmaceutical business), under the name AbbVie, Inc.

As a result of the separation, AbbVie (as subsidiary of AbbVie, Inc.) retained the operation of the utilities located at the former Abbott complex, including the co-generation unit and the boilers, as well as the pharmaceutical plant and the north chemical plant located at the north part of the Barceloneta site. Since AbbVie retained (post-separation from Abbott) the cogeneration unit and the boilers, it is subject to the Prevention of Significant Deterioration ("PSD") permit issued by the US EPA back on January 31, 1989, pursuant to the regulations codified at 40 CFR §52.21 and the Federal Clean Air Act ("CAA"). The 1989 version of the PSD permit superseded the original April 21, 1983 PSD permit. Some of the conditions of the 1989 PSD permit were amended as part of a non-applicability approval on August 10, 1992. All of the conditions of the PSD permit, as amended, were included in AbbVie's July 15, 2016, Title V permit.

Today's Amendment to the 1992 PSD permit:

- 1) Increases the hours of operation of the cogeneration engine from 8,297 hours per year to 8,760 hours per year on a rolling 365-day basis.
- 2) Limits the power generation capacity of the cogeneration engine from 20.8 MW to 17.1 MW. To ensure compliance with this requirement, the permit includes annual emission limits for each pollutant to be complied with on a 12-month rolling basis. This permit does not change any short term emission limits for any pollutant.
- 3) Reduces the maximum allowable sulfur content of the No. 6 fuel oil used in the cogeneration engine from 2% to 1%.
- 4) Removes the three 50 MMBtu/hour boilers and all the related permit conditions from the permit

ENCLOSURE II

ABBVIE, PUERTO RICO

AMENDED PSD PERMIT- November, 2017

November 2017, Statement

AbbVie, after a transfer of ownership from Abbott Laboratories, is the owner responsible for compliance with the conditions of this PSD permit. The cogeneration diesel engine/generator will be limited to produce 17.1 megawatts (MW) of electricity. The cogeneration diesel engine/generator will be allowed to operate for 8,760 hours in a year. The maximum allowed sulfur content of the fuel oil is reduced from 2% to 1% and all the conditions related to three boilers are deleted because the boilers were removed.

The BACT and short term emission limits are provided in Appendix A and annual emission limits are provided in Appendix B.

January 1989, Statement

Abbott Laboratories, Puerto Rico Operations (Abbott), proposed to modify its existing pharmaceutical plant in Barceloneta, PR, by installing a new cogeneration facility to provide both electricity and process steam. The facility, consisting of a low-speed, direct-drive diesel engine, a generator, an oil treatment system and one waste heat recovery boiler, is capable of generating 20.2 megawatts (MW) of electricity and 20,000 pounds per hour of steam.

November 2017 Amended Permit Conditions:

Emission Limitations Applicable to the Cogeneration Diesel Engine (See also Appendix A)

- A. Control of Nitrogen Oxides (NO_x) - AbbVie shall limit NO_x emissions to 4.7 g/hp-hr by redesigning the fuel injector nozzles, reducing turbocharger output, using manifold air cooling, and using water injection with minimum water to fuel ratio of 0.32.
- B. Control of Particulate Matter (PM) - AbbVie shall limit PM emissions to 0.56 grams per horsepower-hour (g/hp-hr) through proper design and maintenance of the diesel engine.
- C. Control of Hydrocarbons (HC) - AbbVie shall limit HC emissions to 0.7g/hp-hr through proper design and maintenance of the diesel engine.
- D. Control of Carbon Monoxide (CO) - AbbVie shall limit CO emissions to 0.6 g/hp-hr through proper design and maintenance of the diesel engine.
- E. Control of Sulfur Dioxide (SO₂) - AbbVie shall burn fuel oil containing no more than 1.0 percent (%) sulfur by weight.
- F. Control of Visible Emissions - AbbVie shall limit the visible emissions from the cogeneration engine such that opacity does not exceed 20%.

Operation Limitations Applicable to the Cogeneration Diesel Engine

- A. The cogeneration diesel engine/generator shall be limited to the capacity of 22,998 horsepower (hp) and 17.1 MW.
- B. The cogeneration diesel engine may operate for 8,760 hours in a year.
- C. The cogeneration diesel engine shall be operated at a cylinder lube oil rate not to exceed 0.43 g/hp-hr except in the following circumstances:
 - 1. During start-up and shut-down;
 - 2. Immediately after disconnecting from the PREPA Grid;
 - 3. During running-in procedures following installation of new or replacement cylinder components, consistent with proper design and maintenance as specified by the manufacturer; and
 - 4. During the following emergency circumstances which Abbott shall use its best efforts to minimize duration: a) abnormal noise in a particular cylinder; b) smoking indication (in the stuffing box oil drain or otherwise) for a particular cylinder; c) stuffing box oil drain analysis for a particular cylinder that indicates an abnormally high content of metal particles; d) operation following failure of a particular cylinder; and e) engine overload for a duration of up to one hour.

Recordkeeping

- A. AbbVie shall record the following:
 - 1. The hours of operation of the cogeneration diesel engine and cogeneration boiler on a daily and rolling 365-day basis.
 - 2. The cylinder lube oil rate of the cogeneration diesel engine, in units g/hp-hour, and the time of the day the reading was taken every eight hours beginning at midnight, on a daily basis. These records shall also be recorded each time the set point is changed. For each and every occurrence (or "excursion") in which AbbVie operates the cogeneration facility with a lube oil rate in excess of 0.43 g/hp-hour, such records shall include; a) the nature of the circumstances surrounding each excursion; b) the duration of each excursion; and c) the corrective measures implemented, or planned to be implemented, to abate future excursions.
- B. Records demonstrating AbbVie's compliance with all permit conditions shall be maintained for five (5) years and summarized in reports which shall be submitted to EPA quarterly. Other records to be maintained shall include logs, reports, computer analyses, calibration charts for manual lube oil set point readings, and any other documentation necessary to demonstrate compliance with all permit conditions.

Reporting Requirements

With the first quarterly summary report AbbVie shall submit the calibration charts for the manual lube oil set point readings. All summary reports shall reflect the following for each month during the quarter:

- A. Total operating hours of the cogeneration diesel engine and the waste heat recovery boiler and the percent of downtime of waste heat boiler on a daily basis on a rolling 365-day basis.
- B. Records of cylinder lube oil rate set point readings for the cogeneration diesel engine, in units of g/hp-hour. Such records shall include an adequate description of the following for each and every occurrence (or "excursion") in which Abbott operates the cogeneration facility with a cylinder lube oil rate in excess of 0.43 g/hp-hour:
 - 1. The nature of the circumstances surrounding each excursion
 - 2. The duration of each occurrence
 - 3. The corrective measures implemented, or planned to be implemented, to abate future excursions.
- C. AbbVie shall submit all reports required by this permit to:
Chief, Permitting Section
Air Programs Branch, EPA Region 2
290 Broadway, New York, NY 10007

Other Conditions

- A. AbbVie shall meet all other applicable federal (including, but not limited to, New Source Performance Standards), state and local requirements.
- B. AbbVie shall, in addition to the above specific conditions, meet all other specifications including, but not limited to, design parameters and emission estimates delineated in the complete PSD application package (complete package dated April 1, 1982) and the Best Available Control Technology (BACT) limitations delineated in Appendix A.

Appendix A

PSD-Affected Pollutants and BACT Summary for AbbVie Puerto Rico Operations Cogeneration Diesel Engine

Emission Unit	PSD-Affected Pollutant	Best Available Control Technology (BACT Limitations)	BACT
Diesel Engine (17.1 megawatt (MW))	NO _x	Emissions shall not exceed 4.7 grams per horsepower-hour (g/hp-hr) - Water to fuel ratio shall be at least 0.32	Redesign of fuel injector nozzles; reduce turbo charger output; manifold air cooling; and water injection
	PM	Emissions shall not exceed 0.56 g/hp-hr	Utilization of proper design and maintenance
	HC	Emissions shall not exceed 0.7 g/hp-hr	Utilization of proper design and maintenance
	CO	Emissions shall not exceed 0.6 g/hp-hr	Utilization of proper design and maintenance
	Sulfur Dioxide	Use of fuel containing no greater than 1% sulfur by weight	Use of low sulfur fuel oil
	Visible Emissions	Opacity shall not exceed 20%	

Appendix B

PSD-Affected Pollutants - Annual Emission Limits for AbbVie, Puerto Rico Operations, Cogeneration facility

Annual Emissions (tons/12-month rolling) =

(Emission Factor (g/hp-hr)) x (Average Power of the Engine (hp)) x (Hours of Operation per 12-month rolling (hrs/12-month rolling) x (1lb/453.592 g) x (1 ton/2000 lb)

PSD-Affected Pollutant	Emission Limit
NOx	1044 tons/12-month rolling
PM	124 tons/12-month rolling
HC	155 tons/12-month rolling
CO	133 tons/12-month rolling
Sulfur Dioxide	693 tons/12-month rolling

