

November 22, 2023

Jonathan Lamb, Senior Environmental Quality Analyst
Department of Environment, Great Lakes, and Energy
Air Quality Division
Cadillac Place
3058 West Grand Boulevard, Suite 2-300
Detroit, Michigan 48202

RE: Violation Notice Response Letter (N7519, Wayne County)

Dear Jonathan Lamb,

This letter is in response to a Violation Notice received by Piramal Pharma Solutions on October 26, 2023, following a site inspection conducted by Mr. Jonathan Lamb, AQD on May 31, 2023. At the time of the inspection, the site was unable to provide the required material usage data and monthly emission calculations for the time period January through April 2023. Unable to provide this data represented a violation of the recordkeeping requirements as specified in Special Conditions FG-MfgAPIs VI. 1 – 6 and FGFACILITY VI. 2a and b of PTI Number 31-12B. During the inspection the site was able to provide Mr. Lamb with the last three years of monthly emission data representing 2020, 2021, and 2022. There were no violations of the permit noted during those times.

The cause of the data gap in the monthly emissions (January to April 2023) is two-fold. First, the site air permit subject matter expert (SME) who had previously compiled and reported all the monthly emission data required by our current air permit separated from the company. As a result, the site was without air permit expertise to support material usages and emission calculations for the time period noted in the Violation Notice. A new air quality SME was hired in July 2023 and began to compile the requisite material usages (batch records) and emission data needed to satisfy the regulatory requirement.

Second, our current Emission Master software license expired compounded by delays in obtaining a new multi-user Emission Master LAN based license. During installation we experienced IT security issues that impacted the use of the LAN based Emission Master software. These set-up issues caused extended software usage delays resulting in the inability to compile data for the time period of January to April 2023.

Once the new software was installed an additional knowledge gap existed concerning the Emission Master software. Due to personnel changes in the onsite expertise to use the software to calculate the monthly emission data and have it available to the inspector, was lagging. This knowledge gap was addressed via training for the new air quality SME and Associate Director of EHS by Mitchell Scientific the software provider.

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This software training was completed in August 2023. The new air quality SME has been diligently compiling the monthly emission data required by the air permit and will be submitted to Jonathan Lamb by November 30, 2023, following a QA/QC check on the calculations and information provided in the monthly reports for January to April 2023.

The recently hired air quality SME will be responsible for compiling and reporting all the monthly material usages and emissions calculations moving forward with the site Associate Director of EHS serving as a back-up. The site is expected to have all material usages and monthly emission calculations completed for 2023, per the current permit requirements, by December 31, 2023. The Piramal site does not anticipate any additional gaps or violations in emission reporting per PTI 31-12B moving forward.

If you have any questions or concerns regarding this response letter, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Jay Brown".

Jay Brown
Associate Director of EHS
Piramal Pharma Solutions
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Riverview, MI 48193
734-282-3370 x1107