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PMI RESEARCH & DEVELOPMENT

February 01, 2018

Elizabeth Harrod
Center for Tobacco Products
Food and Drug Administration
Building 71, Room G355
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Re: MR0000059-MR0000061 - Clarification of the PMP S.A. ongoing "P1 Characterization" Study

Dear Ms. Harrod,

This letter responds to your phone call from Monday, January 22nd, 2018 regarding the ongoing PMP S.A. "P1 Characterization" study. The purpose of this letter is to clarify the intent of the "P1 Characterization" study and provide FDA with additional details about the type of information, purpose and design of the study, report format and approximate size of the data that will be provided to FDA following completion of the study.

The purpose of the study is to provide a comprehensive chemical characterization of all THS aerosol constituents (of concentration ≥ 100 ng/stick) beyond those already identified as being higher in abundance than 3R4F using non-targeted differential screening (NTDS). By way of reference, the purpose of the NTDS, submitted on December 08th, 2017 Amendment, was a comparative analysis of THS aerosol and 3R4F reference cigarette smoke. Any aerosol constituent that was either (a) novel or (b) of greater concentration in THS aerosol compared to 3R4F smoke was evaluated for its toxicological impact. The NTDS identified a number of compounds that were greater in abundance in THS aerosol compared with 3R4F smoke, and some that were unique to THS aerosol. As concluded, none of these compounds were to be present in levels that could be considered of toxicological significance.

In contrast to the NTDS approach, the "P1 Characterization" study will provide a full characterization of the THS aerosol using non-targeted screening (NTS). With this approach, compound identification is not limited to only those compounds identified as being of greater abundance in THS aerosol than in the smoke of 3R4F. The study is being conducted using the same analytical methods as used for NTDS, including two-dimensional gas chromatography with mass spectrometry, gas chromatography with high resolution mass spectrometry and liquid chromatography with high resolution mass spectrometry. The study report will be similar in size to the NTDS studies that were previously submitted to FDA. In term of data, we anticipate that the constituents identified in the THS regular aerosol will comprise approximately 700 ± 50 entries. The data will be presented in tabular form with each entry including, at a minimum:

- the chemical name of the aerosol constituent,
- the CAS number,
- a semi-quantified concentration of each aerosol constituent
- an identification confidence measure for each chemical constituent.

The report is expected to be finalized by end of March 2018 and will be submitted via ESG in a PDF format by mid of April, 2018.

This letter contains confidential commercial and/or trade secret information. Protection of this information from public disclosure is hereby claimed under the applicable provisions of United States law. We request the agency to provide pre-disclosure notification and follow the procedures in 21 C.F.R. §20.61(e) before publicly disclosing any information contained in this amendment.

If you have any further questions or need additional information, please let us know.

Sincerely,

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