



PHILIP MORRIS
PRODUCTS S.A.

August 31, 2018: Amendment to MR0000059-61

Appendix A:

Attachments	
<p>A/J MICE LUNG CANCER STUDY</p> <p>2.7 ADD2_Smoking-related_disease_risk_reduction</p> <p>15020_Study_Results_Overview</p> <p>P15020 THS SR Overview and Signatures</p> <p>P15020 THS SR Part 1_summary results</p> <p>P15020 THS SR Part 2_Descriptive statistics</p> <p>P15020 THS SR Part 3_Inferential statistics</p> <p>P15020 THS SR Part 4_Copy_study-amts_devs</p> <p>P15020 THS SR Part 5_phase report 1_LPT</p> <p>P15020 THS SR Part 6_phase report 2_ABF</p> <p>P15020 THS SR Part 7_phase report 3_MyriadRBM</p> <p>P15020 THS SR Part 8_phase report 4_Histovia</p> <p>P15020 THS SR Part 9_Peer Review Statement</p> <p>P15020 THS SR Part 10</p> <p>SP 15020-01_AJ LC_Omics</p> <p>SP 15020-02_AJ LC_Omics</p> <p>SR 15020 AJ LC Proteomics</p> <p>SR 15020 AJ LC Transcriptomics</p> <p>SR 15020 AJ LC Blood DNA Methylation</p>	



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AMES GLP BACTERIAL REVERSION TEST

RLS-ZRH-2018-344 Ames SP

RLS-ZRH-2018-344 Ames SR

RLS-ZRH-2018-345 Ames SP

RLS-ZRH-2018-345 Ames SR

MICRONUCLEUS ASSAY

RLS-ZRH-2017-661 MN REG SP

RLS-ZRH-2017-661 MN REG SR

VIRUS-FREE CONFIRMATION LETTER

2018-08-30_Virus-free-conf-ltr



PHILIP MORRIS
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August 30, 2018

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Amendment to MR0000059-MR0000061 - Additional information, dated August 30, 2018 - Virus-Free Confirmation

Dear Sir or Madam,

The above-mentioned Amendment including the A/J Mice study package is submitted on a 16 GB USB key, with serial number D66463 2432 / 0D33193.
The size of the submission is 681 MB.

The submission was scanned and certified as virus-free using the Windows Defender Security Center from Windows 10, virus/spyware definition version 1.275.370.0. The definition was last updated on August 29, 2018.

Sincerely,

Malgorzata Wronowska, PhD
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.