

**PARTIAL RESPONSE TO AUGUST 10, 2018 ADVICE/INFORMATION REQUEST
FOR PM0000427-PM0000432 and MR0000068-MR0000073**

Cover Letter and Administrative Information
cvrltr redactions air pr03 mr68-73-pm427-432 18JAN2019.pdf
AIR virus scan statement.pdf
2019 01 11 (b) (4) Scherer.pdf
Deficiency 09
d9-air-mr68-73-pm427-432-final REDACTED.pdf
Deficiency 10
d10-cn49730c-tk-data REDACTED.pdf
d10-cn49730d-tk-data REDACTED.pdf
d10-cn49730e-tk-data REDACTED.pdf
d10-cn49730f-tk-data REDACTED.pdf
d10-cn49730g-tk-data REDACTED.pdf
Deficiency 13
d13aii-csd0901-biomarkers-by-product REDACTED.pdf
d13aii-csd0904-biomarkers-by-product REDACTED.pdf
d13aii-csd0905-biomarkers-by-product REDACTED.pdf
d13aii-csd0914-biomarkers-by-product REDACTED.pdf
d13b (b) (4) -tr-0909-rjr-csd0905-67-973-signed REDACTED.pdf
d13bi (b) (4) -validation-report-sop06 REDACTED.pdf
d13bi (b) (4) -validation-report-sop10 REDACTED.pdf
d13bi (b) (4) -validation-report-sop12 REDACTED.pdf
d13b (b) (4) -validation-report-sop14 REDACTED.pdf
d13b (b) (4) -validation-report-sop18 REDACTED.pdf
d13bi (b) (4) -validation-report-sop19 REDACTED.pdf
d13b (b) (4) -validation-report-sop21 REDACTED.pdf
d13b (b) (4) -validation-report-sop23 REDACTED.pdf
d13bi (b) (4) -validation-report-sop28 REDACTED.pdf
d13bi (b) (4) -validation-report-sop30 REDACTED.pdf
d13bi (b) (4) -validation-report-sop32 REDACTED.pdf

**PARTIAL RESPONSE TO AUGUST 10, 2018 ADVICE/INFORMATION REQUEST
FOR PM0000427-PM0000432 and MR0000068-MR0000073**

d13bi-appendix1-data (b) (4) -tr-0909-csd0905 REDACTED.pdf
d13c-csd0904-bloodbiomarkersbyactualuse REDACTED.pdf
d13c-csd0904-bloodbiomarkersbyactualuse-stats REDACTED.pdf
d13c-csd0904-bloodbiomarkers-polyusecohort REDACTED.pdf
d13c-csd0904-buccalcellbiomarkersbyactualuse REDACTED.pdf
d13c-csd0904-buccalcellbiomarkersbyactualuse-stats REDACTED.pdf
d13c-csd0904-buccalcellbiomarkers-polyusecohort REDACTED.pdf
d13c-csd0904-code-bm-actual-use-equivalents REDACTED.pdf
d13c-csd0904-code-bm-poly-use-group-equivalents REDACTED.pdf
d13c-csd0904-code-statistical-analysis-equivalents REDACTED.pdf
d13c-csd0904-propensityscore-calculation-final REDACTED.pdf
d13c-csd0904-urinebiomarkersbyactualuse REDACTED.pdf
d13c-csd0904-urinebiomarkersbyactualuse-stats REDACTED.pdf
d13c-csd0904-urinebiomarkers-polyusecohort REDACTED.pdf
d13c-hsd0702-biomarkersbyactualuse-programming REDACTED.pdf
d13c-hsd0702-biomarkersbyactualuse-stats REDACTED.pdf
Deficiency 14
d14-corrected-pe-programming-code REDACTED.pdf
d14-csd0901-acrf-corrected-oral-exam-pg REDACTED.pdf
Deficiency 23
d23-air-mr68-73-pm427-432-final REDACTED.pdf
d23-rjrt-snus-complaint-summary REDACTED.pdf
Deficiency 24
d24-air-mr68-73-pm427-432-final REDACTED.pdf
Deficiency 25
d25-ntbm-questionnaire REDACTED.pdf
d25-ntbm-report REDACTED.pdf
d25-ntbm-sas-code REDACTED.pdf
d25-path-raw-data-mapping-spec REDACTED.pdf

**PARTIAL RESPONSE TO AUGUST 10, 2018 ADVICE/INFORMATION REQUEST
FOR PM0000427-PM0000432 and MR0000068-MR0000073**

d25-path-sas-code REDACTED.pdf
d25-tracker-define REDACTED.pdf
Deficiency 29
d29-ca-trend-test-results REDACTED.pdf
d29-cn49730gt-tumor-analysis REDACTED.pdf
Deficiency 30
d30c-2018-10-16-lou-analyses-addl-info-for-fda REDACTED.pdf
define REDACTED.pdf
setup REDACTED.pdf
snuschem REDACTED.pdf
t1to2 gram pouch REDACTED.pdf
t3 mean range REDACTED.pdf
Deficiency 31
r31-34-air-mr68-73-pm427-432-final REDACTED.pdf