

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

Cover Letter and Administrative Information
AIR_virus_scan_statement.pdf
cvrltr_redactions_air_pr01_mr68-73-pm427-432_18JAN2019.pdf
LabstatCoverLetter.pdf
Deficiency 01
d01-air-mr68-73-pm427-432-final_REDACTED.pdf
d01c-16-tensile-bolt-cloth-mesh-screen-coc-REDACTED.pdf
d01c-60-tensile-bolt-cloth-mesh-screen-coc_REDACTED.pdf
d01c-acs-sop-000049-REDACTED.pdf
Deficiency 02
d02-air-mr68-73-pm427-432-final_REDACTED.pdf
d02a-particle-size-complete-data-set_REDACTED.pdf
d02a-rjrt-wi-004754-REDACTED.pdf
d02b-asc-wi-000402_REDACTED.pdf
d02b-portion-wt-test-data-camel-snus-frost_REDACTED.pdf
d02b-portion-wt-test-data-camel-snus-frost-large_REDACTED.pdf
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d02c-asc-wi-000415_REDACTED.pdf
d02c-moisture-ph-test-data-camel-snus-frost_REDACTED.pdf
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d02c-moisture-ph-test-data-camel-snus-winterchill_REDACTED.pdf
d02d-asc-wi-000325_REDACTED.pdf
d02e-(b) (4) -measured-air-permeability_REDACTED.pdf

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

d02e(b) (4) -measured-air-permeability REDACTED.pdf
Deficiency 03
d03a-file-linking-production-runs-to-batches REDACTED.pdf
d03-air-mr68-73-pm427-432-final REDACTED.pdf
d03a-nicotine-sugar-moisture-data-from-supplier REDACTED.pdf
d03a-rais-tpip-000001 REDACTED.pdf
d03a-req-12-agrochemical-residue-test-results REDACTED.pdf
d03a-rjrt-guide-000140 REDACTED.pdf
d03a-rjrt-sop-000614 REDACTED.pdf
d03a-rjrt-sop-000616 REDACTED.pdf
d03a-Warehousing-Manual-Brook-Cove REDACTED.pdf
d03b-asc-wi-000416 REDACTED.pdf
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d03b-asc-wi-000418 REDACTED.pdf
d03b-experimental-tsna-data REDACTED.pdf
d03b-ingredient-cert-camel-snus-frost REDACTED.pdf
d03b-ingredient-cert-camel-snus-frost-large REDACTED.pdf
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FOR PM0000427-PM0000432 and MR0000068-MR0000073**

d03c-asc-tbl-000196 REDACTED.pdf
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Deficiency 04
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Deficiency 05
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FOR PM0000427-PM0000432 and MR0000068-MR0000073**

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Deficiency 06
d06-air-mr68-73-pm427-432-final REDACTED.pdf
d06-catalent-gmp-certification REDACTED.pdf
d06-dissolution-complete-data-set REDACTED.pdf
d06-method-validation-report REDACTED.pdf
d06-pdr-atm-rgc-0001-method REDACTED.pdf
d06-raw-data-pdf-report-from-catalent REDACTED.pdf
d06-raw-excel-from-catalent-frost REDACTED.pdf
d06-raw-excel-from-catalent-frost-large REDACTED.pdf
d06-raw-excel-from-catalent-mellow REDACTED.pdf
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d06-raw-excel-from-catalent-robust REDACTED.pdf
d06-raw-excel-from-catalent-winterchill REDACTED.pdf
Deficiency 07
d07a-rjrt-wi-004121 REDACTED.pdf
d07a-rjrt-wi-004181 REDACTED.pdf
d07b-rjrt-wi-004227 REDACTED.pdf
Deficiency 08
d08-air-mr68-73-pm427-432-final REDACTED.pdf
d08-air-mr68-73-pm427-432-rdm-corrections REDACTED.pdf
d08-rdm-trm-2018-192-b REDACTED.pdf

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FOR PM0000427-PM0000432 and MR0000068-MR0000073**

Deficiency 12
d12-air-mr68-73-pm427-432-final REDACTED.pdf
d12-tba-504-09 REDACTED.pdf
Deficiency 15
d15-data-programming-code REDACTED.pdf
Deficiency 16
d16-air-mr68-73-pm427-432-final REDACTED.pdf
d16-data-entry-guidelines-csd1010 REDACTED.pdf
Deficiency 17
d17-mr68-73-pm427-432-final REDACTED.pdf