



October 19, 2018

NOT SUBSTANTIALLY EQUIVALENT

Seneca Manufacturing Company
ATTENTION: Marc Scheineson, Esq.
Regulatory Counsel, Alston & Bird, LLP
950 F Street, NW
Washington, DC 20004

FDA Submission Tracking Numbers (STNs): MULTIPLE STNs, SEE APPENDIX A

Dear Mr. Scheineson:

The Food and Drug Administration (FDA) completed review of your Reports Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Reports), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the tobacco products specified in Appendix A.

Based on our review of your SE Reports, we find the new tobacco products are not substantially equivalent to the corresponding eligible predicate tobacco products specified in Appendix A.

We have described below the basis for this determination.

1. All of your SE Reports indicate that you remanufactured the predicate products to the closest specifications possible to match the original grandfathered predicate products except for the use of (b) (4) low-ignition propensity (LIP) fire standard complaint paper(FSC). However, all of your SE Reports indicate higher levels of (b) (4) tobacco (94-126%) for the new products compared to the corresponding predicate products. You needed to demonstrate that increases in (b) (4) tobacco do not cause the new products to raise different questions of public health and one way you may have demonstrated this is by providing PAH or TSNA smoke data for the new and corresponding predicate products.
2. All of your SE Reports show an increase in (b) (4) quantities in the new product. You acknowledge that acetaldehyde is produced upon the pyrolysis of (b) (4) but you disagreed that benzene is produced upon pyrolysis. You stated that a recent FDA toxicology review of FSC paper concluded that new tobacco products containing FSC paper do not raise different questions of public health compared to predicate products that do not contain FSC paper. However, conclusions of previous scientific reviews are based solely on data and scientific evidence provided for the specified SE Reports, and, therefore, are not appropriate for extrapolation for your current SE Reports. You may have provided evidence to account for this change in ingredient by providing acetaldehyde or benzene smoke data for the new and corresponding predicate products.
3. All of your SE Reports address the increased (b) (4) quantities by explaining that there are two tobacco blends for the new products which have 0.1-1.5% (b) (4) added to the blends. You explained that the predicate products have relatively low levels of (b) (4) added to the top-

flavors. You agreed that acrolein is produced upon the pyrolysis of (b) (4) but disagreed with the statement that formaldehyde is formed in any appreciable amount. You also cited references that report no formation of benzene from (b) (4), however those references were not specific to the tobacco products currently under review. You stated that upon pyrolysis, (b) (4) is only a minor contributor to the formation of acrolein. However, you have not provided adequate evidence for the increase in (b) (4). One way this may have been addressed is by providing acrolein, formaldehyde or benzene from mainstream smoke for the new and corresponding predicate products to support these statements.

4. SE0001382 and SE0001409-SE0001421 contain some quantities of (b) (4) that require further explanation. You provide ranges for the amount of (b) (4) present. However, in order to evaluate the new and predicate tobacco products, you needed to provide the quantitative target values of (b) (4) to determine if the differences in (b) (4) levels cause the new products to raise different questions of public health.
5. SE0001362, SE0001364, SE0001365, SE0001367, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001417, SE0001419, SE0001421 have significantly higher values of tar (17-102%) and nicotine (28-153%) as compared to the corresponding predicate products. Moreover, the carbon monoxide levels (ISO) for the new products in SE0001362, SE0001364, SE0001365, SE0001367, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001421 were determined to be higher by 17-89% than the corresponding predicate products. However, you failed to provide an explanation or rationale for why these increases do not cause the new products to raise different questions of public health.
6. All of your SE Reports have a discrepancy in the data provided that needs additional clarification. The product names used in the tables from your June 20, 2016 amendment to the SE Reports did not include the full product names, leaving off the packaging terms "soft pack" or "box". For SE0001368, SE0001372, SE0001410, SE0001412, SE0001414, SE0001416, SE0001418, and SE0001420, you stated that the new products were not tested. However, the test results from (b) (4) were clearly marked as the box versions of these products (SE0001367, SE0001371, SE0001409, SE0001411, SE0001413, SE0001415, SE0001417, and SE0001419). The test results were also clear for SE0001364, SE0001375, SE0001382, and SE0001421, because the SE Reports only included a box version for these new products. However, for SE0001362, SE0001363, SE0001365, SE0001366, SE0001369, SE0001370, SE0001373, and SE0001374, it unclear if the abbreviations in the tables for the new products represent testing done on the soft pack version or the box version. The cigarettes used in soft pack and box products are often identical and it could be appropriate for a single set of tests to apply to both the soft pack and box versions of these new products. While the information provided in the SE Reports does not indicate any differences between the cigarettes in soft pack and box versions of these products, the test results cannot be assumed to apply to both new products without verification that the soft pack and box versions actually contain identical cigarettes. Likewise, without the full name for these products, it cannot be assumed that the test results apply to one of the new products or to the other. Therefore, for SE0001363, SE0001366, SE0001368, SE0001370, SE0001372, SE0001374, SE0001409, SE0001412, SE0001414, SE0001416, SE0001418, SE0001420 you needed to provide clear labeling for these products and indicate if testing was conducted, including measurements for TNCO yields and puff count test results.

7. All of your SE Reports include design parameter specifications, but do not include data confirming that specifications are met. You submitted tables in response to the December 24, 2015 Preliminary Finding letter for data that do not appear to be test data. For example, Tables 2b, 2h, and 2j are identical to the specification tables provided for those design parameters (Tables 1a, 1b, and 1c respectively). Not only is each numerical value identical between the corresponding tables, but the column headers of target, actual, upper, and lower are identical. Similarly, for Tables 2i and 2l, the target values provided for the new and predicate products are the same as the target specifications. Likewise, the upper values provided are the same as the upper range limit specifications and the lower values provided are the same as the lower range limit specifications. Test data is used to confirm that the new and predicate products conform to specifications. Cigarettes that are not produced to specifications could cause the new products to raise different questions of public health. You needed to provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for the following design parameters for each new and predicate product:
- Cigarette draw resistance (mm H₂O)
 - Filter denier per filament (dpf)
 - Filter total denier (g/9000m)
 - Filter pressure drop (mm H₂O)

Certificates of analysis (COAs) from the material supplier may have satisfied this concern by providing the target specification, quantitative acceptance criteria, parameter units, test data average value, and either the standard deviation of the test data, or the minimum and maximum values of the test data.

8. SE00013365, SE00013366, SE00013367, SE00013368, SE00013373, SE00013374, SE00013375, SE00013413, SE00013414, SE00013415, SE00013416, and SE00013421 include values for the target specification for filter ventilation for the predicate products. However, you provide a value of NM (i.e., not measured) for the target specifications and for the test data for filter ventilation for the new product, but you do not provide scientific evidence and a rationale for why you do not specify or measure filter ventilation. Furthermore, you did not provide upper and lower range limits for the new and predicate products. A difference in filter ventilation may affect smoke constituent yields. You needed to provide target specifications and upper and lower range limits for filter ventilation for the new and predicate products or provide scientific evidence and a rationale for why the new and predicate products do not need to have filter ventilation specifications. Additionally, you needed to provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for filter ventilation for each new product.
9. All of your SE Reports provide target specifications and upper and lower range limits for cigarette paper band porosity for the new products but provide values of NM (i.e., not measured) for the test data for cigarette paper band porosity. You do not provide scientific evidence and a rationale for why you do not measure cigarette paper band porosity, and the certificate of analysis (COA) from [b] (4) for the cigarette paper used on the new products do not include information regarding the cigarette paper band porosity. Test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with specifications and produced to specifications could cause the new products to raise different questions of public health. You needed to provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance

criteria, data sets, and a summary of the results for the cigarette paper band porosity for each new product.

Certificates of analysis (COAs) from the material supplier may have satisfied this concern by providing the target specification, quantitative acceptance criteria, parameter units, test data average value, and either the standard deviation of the test data, or the minimum and maximum values of the test data.

10. All of your SE Reports provide target specifications and upper and lower range limits for filter density for the new and predicate products but provide values of NM (i.e., not measured) for the test data for filter density. You do not provide scientific evidence and a rationale for why you do not measure filter density. Test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with specifications and produced to specifications could cause the new products to raise different questions of public health. You needed to provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for the filter density for each new product.

Certificates of analysis (COAs) from the material supplier may have satisfied this concern by providing the target specification, quantitative acceptance criteria, parameter units, test data average value, and either the standard deviation of the test data, or the minimum and maximum values of the test data.

11. All of your SE Reports provide information on the filter of the new and corresponding predicate tobacco products. However, some of your SE Reports include filter differences that may cause the new product to raise different questions of public health as indicated below:
 - a. A 7%-40% decrease in filter pressure drop in SE0001362–SE0001365, SE0001367–SE0001375, SE0001382, SE0001411, SE0001412, and SE0001415–SE0001421
 - b. A 33% decrease in filter length in SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420

Decreases in filter pressure drop and filter length may result in reduced filter efficiency, and in turn, an increase in tar and nicotine levels. You did not provide scientific evidence and a rationale as to why the decreases in filter pressure drop and the decreases in filter length do not cause the new products to raise different questions of public health. Demonstrating that the decreases in filter pressure drop and filter length do not result in increased smoke constituent yields could satisfy this deficiency; however, every tar and nicotine value that you provided using the ISO smoking regimen showed an increase between the new and corresponding predicate products. Therefore, you needed to provide scientific evidence and a rationale as to why the decreases in filter pressure drop and the decreases in filter length do not cause the new products to raise different questions of public health.

12. All of your SE Reports provide information on the tobacco rod density and tobacco oven volatiles of the new and corresponding predicate tobacco products. However, some of your SE Reports include design parameter differences that may cause the new product to raise different questions of public health as indicated below:

- a. 7% decrease in tobacco rod density (SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420)
- b. 13% decrease in tobacco oven volatiles (SE0001382 and SE0001409–SE0001421)

Design parameter differences can affect the performance and smoke constituent yields of the cigarettes. You did not provide scientific evidence and a rationale as to why the decreases in tobacco rod density and tobacco oven volatiles do not cause the new products to raise different questions of public health. Demonstrating that the decreases in tobacco rod density and tobacco oven volatiles do not result in increased smoke constituent yields could satisfy this deficiency; however, all tar and nicotine value that you provided using the ISO smoking regimen showed an increase between the new and corresponding predicate products. Therefore, you needed to provide scientific evidence and a rationale as to why the decreases in tobacco rod density and tobacco oven volatiles do not cause the new products to raise different questions of public health.

13. All of your SE Reports include test data for the tobacco oven volatiles for the predicate products. For each of the predicate products, the value that was provided for the tobacco oven volatiles average was below the lower range limits that were provided. You needed to explain why the test data value provided for tobacco oven volatiles for each of the predicate products was below the lower reject limit.
14. SE0001362, SE0001364, SE0001369, SE0001371, SE0001372, SE0001411, SE0001412, SE0001419, and SE0001420 include tobacco filler mass data for the new products where the upper value is higher than the upper range limit from the specifications. Additionally, for SE0001363, SE0001365, SE0001366, SE0001368, SE0001370, SE0001373, SE0001374, SE0001375, SE0001382, SE0001409, SE0001410, SE0001413, SE0001414, SE0001415, SE0001417, SE0001418, and SE0001421, you include tobacco filler mass data for the new products where the lower value is lower than the lower range limit from the specifications. You needed to explain why the test data provided for tobacco filler mass for the new products included values that fall outside of the upper or lower range limits.

You did not provide sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that these new tobacco products are not substantially equivalent to an appropriate predicate tobacco product. Upon issuance of this order, your tobacco products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

Additionally, FDA requests that within 15 days of this letter you submit a plan detailing the steps you plan to take to ensure that these misbranded and adulterated products are not further distributed, imported, sold, marketed, or promoted in the United States by others. Your plan should include information sufficient to distinguish these misbranded and adulterated products from legally marketed tobacco products, including, but not limited to lot numbers, manufacturing codes, and manufacturing dates. The plan should also include a list of your direct accounts, and contain their contact information. Submit your plan to the address below with a cover letter that includes the following text in the subject line:

COMPLIANCE PLAN for SE0001362-SE0001375, SE0001382, SE0001409-SE0001421

FDA will post product identifying information on a list of tobacco products that are adulterated and misbranded due to an NSE order, available to the public at <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm371765.htm>.

We remind you that you are required to update your listing information in June and December of each year under section 905(i)(3) of the FD&C Act. As part of this listing update, under section 905(i)(3)(B) of the FD&C Act, you must provide information on the date of discontinuance and product identity for any product you discontinue.

If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)¹ using eSubmitter (<http://www.fda.gov/ForIndustry/FDAeSubmitter>), or mail it to:

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

The CTP Portal and FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutctp/contact/default.htm>); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

We ask that your request be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE001362-SE0001375, SE00001382, SE0001409-SE0001421**. In addition, we ask you to identify each basis for the request and include all information on which you wish your request to be based; it may not contain any new data or analysis that was not part of your SE Reports.

To legally market the new products described in this application, they must comply with the requirements in section 910(a)(2)(A) of the FD&C Act.

See the following website for additional information on these three pathways:
<https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/default.htm>

¹ The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

If you have any questions, please contact James Lumalcuri, MSW, Regulatory Health Project Manager, at (301) 796 - 4564 or james.lumalcuri@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -
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Date: 2018.10.19 14:28:09 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Appendix A

List of new tobacco products that FDA has determined are not substantially equivalent when compared to its predicate tobacco product.

| Common Attributes of SE Reports | |
|--|-----------------------------------|
| Date of Submission: | March 21, 2011 |
| Date of Receipt: | March 22, 2011 |
| Product Manufacturer: | Seneca Manufacturing Company |
| Product Category: | Cigarettes |
| Product Sub-Category: | Combusted, Filtered |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001362 |
| Product Name: ² | Heron Red 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter: ³ | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name: ² | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter: ³ | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001363 |
| Product Name: ² | Heron Red 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter: ³ | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name: ² | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter: ³ | 7.89 mm |
| Ventilation: | Not Provided |

² Brand/sub-brand or other commercial name used in commercial distribution.

³ The applicant submitted the circumference which allowed for a calculation of diameter.

| New Tobacco Product Specific Attributes | |
|--|-----------------------------------|
| Submission Tracking Number | SE0001364 |
| Product Name:2 | Heron Red Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001365 |
| Product Name:2 | Heron Gold 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-----------------------------|
| Submission Tracking Number | SE0001366 |
| Product Name:2 | Heron Gold 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001367 |
| Product Name:2 | Heron Gold Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------|
| Submission Tracking Number | SE0001368 |
| Product Name:2 | Heron Gold Kings Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001369 |
| Product Name:2 | Heron Menthol 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------|
| Submission Tracking Number | SE0001370 |
| Product Name:2 | Heron Menthol 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001371 |
| Product Name:2 | Heron Menthol Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------------|
| Submission Tracking Number | SE0001372 |
| Product Name:2 | Heron Menthol Kings Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001373 |
| Product Name:2 | Heron Menthol Gold 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------------|
| Submission Tracking Number | SE0001374 |
| Product Name:2 | Heron Menthol Gold 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001375 |
| Product Name:2 | Heron Menthol Gold Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-----------------------------------|
| Submission Tracking Number | SE0001382 |
| Product Name:2 | Heron CRIMSON 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001409 |
| Product Name:2 | Sands Red 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-----------------------------------|
| Submission Tracking Number | SE0001410 |
| Product Name:2 | Sands Red 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001411 |
| Product Name:2 | Sands Red Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-----------------------------------|
| Submission Tracking Number | SE0001412 |
| Product Name:2 | Sands Red Kings Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Full Flavor 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001413 |
| Product Name:2 | Sands Gold 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-----------------------------|
| Submission Tracking Number | SE0001414 |
| Product Name:2 | Sands Gold 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001415 |
| Product Name:2 | Sands Gold Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------|
| Submission Tracking Number | SE0001416 |
| Product Name:2 | Sands Gold Kings Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | None |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001417 |
| Product Name:2 | Sands Menthol 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------|
| Submission Tracking Number | SE0001418 |
| Product Name:2 | Sands Menthol 100s Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001419 |
| Product Name:2 | Sands Menthol Kings Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |

| New Tobacco Product Specific Attributes | |
|--|-------------------------------------|
| Submission Tracking Number | SE0001420 |
| Product Name:2 | Sands Menthol Kings Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 84 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |
| New Tobacco Product Specific Attributes | |
| Submission Tracking Number | SE0001421 |
| Product Name:2 | Sands Menthol Blue 100s Box |
| Package Type: | Hard Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Length: | 98 mm |
| Diameter:3 | 7.86 mm |
| Ventilation: | Not Provided |
| Predicate Tobacco Product Specific Attributes | |
| Product Name:2 | Heron Menthol Light 100's Soft Pack |
| Package Type: | Soft Pack |
| Package Quantity: | 20 Cigarettes |
| Characterizing Flavor: | Menthol |
| Eligibility Status: | Grandfathered |
| Length: | 99 mm |
| Diameter:3 | 7.89 mm |
| Ventilation: | Not Provided |