U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

August 23, 2018

NOT SUBSTANTIALLY EQUIVALENT

Joseph Anderson d/b/a Smokin Joes
ATTENTION: Marc Scheineson, Esq.
Alston & Bird, LLP
950 F Street, N.W.
Washington, D.C. 20004

FDA Submission Tracking Number (STN): 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 our basis for this determination.

1. All of your SE Reports provide information about the tobacco and ingredients added to the tobacco in the new and predicate products, but limited information on the grades were provided. The information provided for the tobacco did not include sufficient detail to fully identify the composition of the new and predicate products. For example, we are unable to understand the meaning of the tobacco grades: (b) (4) [redacted]. Furthermore, (b) (4) [redacted] is listed twice for the (b) (4) [redacted] tobacco for the new product. It is not clear why one grade is listed twice within the same type of tobacco. We needed additional information that uniquely identifies the tobacco and other ingredients used in the new and predicate products to assess whether there are any differences between the new and predicate product and, if so, to determine whether those differences do not cause the new product to raise different questions of public health. You did not provide a detailed list uniquely identifying information for all non-tobacco ingredients (e.g., CAS #, grade/purity, function) and for all tobacco (e.g., tobacco grading system) needed to fully characterize the new and predicate products. If composition differences exist between the new and predicate products, you would also need to provide a rationale for each difference with evidence and a scientific discussion for why the differences do not cause the new product to raise different questions of public health.

2. SE0003006, SE0003012, SE0003014, SE0003015, and SE0003020 – SE0003023 provide data comparing the quantities of HPHCs in the new and remanufactured predicate products, also known as a surrogate predicate product, by submitting the amendments dated March 10, 2017 and July 10, 2017. However, your SE Report lacks HPHC yields to fully evaluate changes

in [redacted] and [redacted] in the new product compared to the surrogate predicate product. These ingredient differences between the new and surrogate predicate product may cause the new product to raise different questions of public health. You needed to provide scientific evidence and rationale to address why these differences do not cause the new products to raise different questions of public health. One way you may have provided such evidence is by providing measured mainstream smoke yields for formaldehyde and acrolein.

These HPHC measurements would have helped to determine whether these ingredients cause the new product to raise different questions of public health. For example, mainstream smoke yields of formaldehyde and acrolein are needed because [redacted] may be thermally decomposed to formaldehyde and acrolein, while [redacted] can be pyrolyzed to acrolein. Higher levels of [redacted] and [redacted] in tobacco products may result in higher quantities of formaldehyde and acrolein in mainstream smoke. The measurement of the HPHC quantities under both ISO and CI smoking regimens would best characterize the delivery of the constituents from these products. FDA suggests that appropriate measures be taken to minimize data variability and systematic bias. The suggested measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. If you decided to measure select HPHCs, you needed to provide the following information about all HPHC testing so that FDA was able to fully evaluate the differences in HPHC quantities between the new and remanufactured predicate products:

a. Reference product datasets (e.g., 1R6F)
b. Quantitative test protocols and method used
c. Testing laboratory and their accreditation(s)
d. Length of time between date(s) of manufacture and date(s) of testing
e. Number of replicates
f. Standard deviation(s)
g. Complete data sets
h. A summary of the results for all testing performed
i. Storage conditions prior to initiating testing If your test methods are national or international test standards, identify any deviations from those standards

3. All of your SE Reports list ingredient quantities as percentages but do not specify the original units of the numerator and denominator, or define the denominator (e.g., per cigarette, per gram). For some ingredients listed, your SE Report does not provide any quantities. In order for FDA to fully understand the composition of the new and predicate products and make a determination of substantial equivalence, you needed to provide ingredient quantities as mass per unit of use (e.g., mg/cigarette).

4. All of our SE Reports provide conflicting tobacco blend quantities in the “Tobacco Blend” and “Design Feature” in the original SE Report compared to the amendment to your SE Report. Specifically, the total weight of tobacco reported in the “Tobacco Blend” section differs from the “Tobacco Weight per Cigarette” given in the “Design Feature” tab. In order to understand the tobacco blend, clarification regarding the total amount of tobacco and the quantities of each tobacco type contained in the blend for the new and predicate products is needed.

5. All of your SE Reports include data comparing the quantities of HPHCs in the new and remanufactured predicate products. However, your SE Report lacks detailed information of methods [redacted] used by [redacted], which is necessary to

fully evaluate the data. You needed to provide the following information about the HPHC testing so that we can fully evaluate the HPHC data:

a. Reference product datasets (e.g., 1R6F)
b. Quantitative test protocols and method used
c. A summary of the results for all testing performed

6. All of your SE Reports list mainstream smoke yields of TNCO and three HPHCs (acetaldehyde, benzene and B[a]P) under ISO and CI smoking regimens. However, there are discrepancies between the data sets in the (b) (4) Report and Exhibit A of your July 10, 2017 amendment. For example, in the (b) (4) report, the nicotine level in mainstream smoke under the ISO and CI regimen is different than what is reported in Exhibit A. You needed to explain the data discrepancies in your amendment and identify the correct data sets for FDA to determine whether the differences in HPHC yields do not cause the new product to raise different questions of public health.

7. All of your SE Reports contain some quantities of ingredients that require additional explanation. For example, the values of (b) (4) in seam adhesive are reported as (b) (4) mg/cigarette and (b) (4) mg/cigarette for the new and predicate products, respectively, and the quantities of (b) (4) in tipping adhesive are (b) (4) mg/cigarette for the new product. You needed to provide justification for reporting range quantities for these ingredients.

8. All of your SE Reports compared the HPHC data of the "present day predicate" to that of the new product. You state that the "present day predicate" was constructed with the same materials and components as all of the Smokin Joes product marketed on February 15, 2007. However, you did not submit documentation demonstrating that the remanufactured predicate product at present day reflects the grandfathered predicate product at the time of the original manufacture including a side by side comparison of the ingredients, tobacco blends, and product design parameters. You needed to confirm whether there are any differences between the "present day predicate" and grandfathered predicate product. If differences exist in the product composition and design parameters between the "present day predicate" and grandfathered predicate products, you would need to provide detailed information of the differences for FDA to determine whether the "present day predicate" are reflective of the grandfathered predicate product.

9. All of your SE Reports provide information on the design parameters for the new and predicate products. However, your SE Report does not include all of the design parameters needed to fully characterize the new and predicate products. In order to adequately characterize the products, key design parameters need to be compared. Additionally, your SE Report indicates that FSC cigarette paper is used in the new product. However, the tables you provided list "band width/spacing (mm)" and do not clearly indicate whether the target specification and range limits for "band width/spacing (mm)" correspond to band width or to band space. Accordingly, clarification regarding your use of the term "band width/spacing (mm)" is needed. Furthermore, you provided "band diffusion (cm/s)" rather than band porosity (CU). Band diffusion is not interchangeable with band porosity.

   Therefore, you needed to provide the actual (not approximate) target specification and upper and lower range limits for *all* of the following cigarette design parameters for the new or predicate products, as indicated:

a. Tobacco filler mass (mg) [predicate product only]
b. Cigarette paper band porosity (CU) [new product only]
c. Cigarette paper band width (mm) [new product only]
d. Cigarette paper band space (mm) [new product only]

In addition, you needed to provide the upper and lower range limits for *all* of the following cigarette design parameters for the new and predicate products, as indicated:

e. Cigarette circumference (mm) [predicate product only]
f. Cigarette draw resistance (mm H_2O)
g. Tobacco rod density (g/cm^3) [predicate product only]
h. Total denier (g/9,000m)
i. Denier per filament (DPF)
j. Filter density (g/cm^3)
k. Filter length (mm)
l. Filter ventilation (%)

For each of the above parameters, you needed to provide the necessary data on a per unit of product basis (e.g., filter length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

If a difference exists between the new and predicate products, you would need to provide a rationale for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new product to raise different questions of public health.

10. All of your SE Reports include design parameter specifications but do not include data confirming that specifications are met. 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 *all* of the following cigarette design parameters for the new and predicate product unless otherwise indicated:

a. Cigarette draw resistance (mm H_2O)
b. Tobacco filler mass (mg)
c. Tobacco oven volatiles (OV) (%)
d. Filter ventilation (%)
e. Cigarette paper base paper basis weight (g/m^2)
f. Cigarette paper base paper porosity (CU)
g. Cigarette paper band porosity (CU) [new product only]
h. Total denier (g/9,000m)
i. Denier per filament (DPF)
j. Filter density (g/cm^3)
k. Filter pressure drop (mm H_2O)

For each of the above parameters, you needed to provide the data on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

Certificates of analysis from the material supplier may have satisfied this issue. If you chose to address this issue by providing certificates of analysis for any of the parameters listed above, the certificates of analysis needed to include a 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. Additionally, for the design parameters listed above that were tested according to national or international standards, you needed to identify the standards and state what deviations, if any, from the standards occurred.

11. All of your SE Reports indicate that you may employ the use of multiple materials for cigarette paper for material supply security. However, it is unclear whether you use multiple materials for cigarette base paper, filter tow, plug wrap, tipping paper, inks, and seam adhesives for the new and predicate products, based on the material ingredients information provided in your SE Report. You needed to clarify the materials for which multiple interchangeable materials are used in the new and predicate products. In accordance with section 910(a)(1)(B) of the FD&C Act, each product modification, including use of an alternate material, constitutes a new tobacco product. A material is an alternate material if, for example, it has any difference in composition (e.g., ingredients, additives, and biological organisms). Each identified new and predicate product must consist of a single combination of cigarette base paper, filter tow, plug wrap, tipping paper, inks, and seam adhesive materials. Based on the components which you confirm employ the use of multiple interchangeable materials, you needed to identify the following:

    a. Every unique material combination in the predicate product that you are comparing to the new product.
    b. Every unique material combination in the new tobacco product. Each specific combination of materials will be considered a single new tobacco product and evaluated individually.

    You needed to provide the list of ingredients and ingredient quantities for each identified material in each new and predicate product. Additionally, you needed to provide the target specifications and upper and lower range limits for *all* of the following design parameters for each material in the new and predicate products:

    c. Cigarette base paper basis weight
    d. Cigarette base paper porosity
    e. Cigarette base paper band width
    f. Cigarette base paper band space
    g. Filter total denier
    h. Filter denier per filament
    i. Filter density
    j. Filter pressure drop
    k. Filter length
    l. Filter ventilation
    m. Tipping paper length
    n. Cigarette draw resistance

You also 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 *all* of the following design parameters for each material in the new and predicate products:

o. Cigarette base paper basis weight
p. Cigarette base paper porosity
q. Cigarette band porosity
r. Filter total denier
s. Filter denier per filament
t. Filter density
u. Filter pressure drop
v. Filter ventilation
w. Cigarette draw resistance

Certificates of analysis from the material supplier may have satisfied this issue. If you chose to address this issue by providing certificate of analysis for any of the parameters listed above, the certificate of analysis needed to include 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.

Refer to the Preliminary Finding letter issued by FDA on February 13, 2018, which provided instructions/options on some approaches that could be used to address this issue.

12. SE0002998, SE0003000, SE0003001, SE0003014, SE0003022, and SE0003023 indicate that the denier per filament, filter density, filter length, cigarette circumference, and tobacco rod density decreased in the new product and the overall cigarette draw resistance increased in the new product. Because the combined differences to denier per filament, filter density, filter length, cigarette circumference, and tobacco rod density would be expected to result in similar and proportional differences to overall cigarette draw resistance, it is unclear why the overall cigarette draw resistance increased. Therefore, in order to fully characterize the new and predicate products, you needed to confirm that the values provided for overall cigarette draw resistance are accurate. If the values are not accurate, you needed to provide new values for overall cigarette draw resistance for the new and predicate products. If any difference exists between the new and predicate products, you needed to provide a justification and scientific rationale to demonstrate that the difference does not cause the new product to raise different questions of public health.

13. SE0003005, SE0003006, SE0003012, SE0003015, SE0003020, and SE0003021 indicate that the tipping paper length for the new and predicate product is 27mm, while the filter plug length is 30mm. It is unclear why the provided tipping paper length is less than the provided filter plug length because tipping paper typically extends beyond the filter plug to secure the filter plug to the tobacco rod. To fully characterize the design parameters of the new and predicate product, you needed to clarify the length of the tipping paper. If a difference exists between the new and predicate product, you needed to provide a scientific discussion and rationale to justify why the difference does not cause the new product to raise different questions of public health.

14. SE0002998, SE0003000, SE0003001, SE0003014, SE0003022, and SE0003022 indicate that the tobacco rod packing density decreased by 11 % in the new product. Decreased tobacco rod packing density may decrease the filtration through the tobacco rod, thereby increasing the smoke constituent yields of the cigarette and causing the new product to raise different

questions of public health. While you provided select HPHCs, complete information on the analytical methods was not provided in order to determine the validity of the data, therefore limiting a complete analysis on the influence on tobacco rod packing density on HPHC yields. Therefore, you needed to provide scientific evidence and rationale for why the decrease in tobacco rod packing density does not cause the new product to raise different questions of public health.

15. All of your SE Reports indicate that the base paper porosity decreased by 8 % in the new product. Decreased base paper porosity may result in increased smoke constituent yields through decreased air dilution of the smoke. While you provided select HPHCs, complete information on the analytical methods was not provided in order to determine the validity of the data, therefore limiting a complete analysis on the influence on base paper porosity on HPHC yields. Therefore, you needed to provide scientific evidence and rationale for why the decreased base paper porosity does not cause the new product to raise different questions of public health.

16. SE0002998, SE0003000, SE0003001, SE0003014, SE0003022, and SE0003023 indicate that there are differences in the filter design parameters of the new and predicate products. The denier per filament, filter density, filter length, decreased in the new product while the pressure drop decreased in the new product of SE0002998 and increased in the new products in SE0003000, SE0003001, SE0003014, SE0003022, and SE0003023. Because the differences to denier per filament, filter density, and filter length would be expected to result in similar and proportional differences to filter pressure drop, it is unclear why the pressure drop increases in one of these SE Reports but decreases in the other five SE Reports. Therefore, in order to fully characterize the new and predicate products, you needed to provide a scientific explanation to clarify the unexpected differences to filter pressure drop among the other collective differences to filter design parameters in the new product.

17. SE0002998, SE0003000, SE0003001, SE0003005, SE0003006, SE0003012, SE0003014, and SE0003020 – SE0003023 indicate that there are differences in numerous filter design parameter specifications including the following:

    a. SE0002998: a (b) (4) decrease in filter denier per filament, a less than 5 % decrease in filter density, a 11 % decrease in filter pressure drop and a 20 % decrease in filter length
    b. SE0003000, SE0003001, SE0003014, SE0003022, and SE0003023: a (b) (4) decrease in filter denier per filament, a 38 % increase in filter pressure drop, and a 20 % decrease in filter length
    c. SE0003014: 8.3 % decrease in filter density
    d. SE0003005, SE0003006, SE0003012, SE0003020, and SE0003021: a 11 % increase in filter pressure drop and a 5.0 % decrease in filter density

    Some of these differences have the potential to cause the new product to raise different questions of public health, while others do not. The combination of the differences in the filter design parameters (i.e., filter denier per filament, filter density, filter pressure drop, filter length) may impact smoke constituent yields of the new product. Therefore, you needed to provide scientific evidence and rationale to demonstrate that the combination of differences to the filter design parameters do not cause the new product to raise different questions of public health. One potential way you may have addressed this issue would be to provide target specifications, upper and lower range limits, and complete 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 efficiency (%) of the new and predicate product.

18. All of your SE Reports provide average values for puff count for the new and predicate products, but does not provide test protocols or data sets for the new and predicate products for puff count. An increase in puff count may increase smoke constituent yields, thereby causing the new products to raise different questions of public health. While you provided select HPHCs, complete information on the analytical methods was not provided in order to determine the validity of the data, therefore limiting a complete analysis on the influence of puff count on HPHC yields. You needed to provide complete test data in order to fully characterize the new and predicate products. Additionally, you needed to provide the test protocol and data sets for puff count for the new and predicate products and scientific evidence and rationale for why any differences in the puff count does not cause the new product to raise different questions of public health.

19. All of your SE Report indicate ingredients added or increased in the combustible parts of the new products (tobacco, cigarette paper and seam adhesive) that could cause the new products to raise different questions of public health. You submitted HPHC testing data for all the new and remanufactured ('present day') predicate products in the amendment received on July 10, 2017. However, this HPHC data is inadequate because you did not provide sufficient details on the testing methods, protocols, laboratory and its accreditation, etc., and you did not provide enough information (e.g., materials, ingredients, tobacco blend) comparing the remanufactured predicate products used for the HPHC testing to the originally manufactured predicate products. As a result of the former, HPHC data from the remanufactured predicate products cannot be used in place of HPHC data from the originally manufactured products.

    Despite the foregoing, and proceeding on the assumption that the HPHC data is adequate, the HPHC values you provided indicate apparent increases in the new products when compared with the corresponding predicate products for the SE Reports below:

    Acetaldehyde
    ISO: SE0003000 (22.02 %), SE0003001 (22.02 %)
    HCI: SE0003000 (23.05 %), SE0003001 (23.05 %), SE0003012 (16.92 %), SE0003014 (16.81 %)

    Benzene
    HCI: SE0002998 (10.74 %), SE0003000 (15.79 %), SE0003001 (15.79 %), SE0003012 (25 %)

    Benzo(a)pyrene
    ISO: SE0002998 (53.17 %), SE0003014 (54.29 %)
    HCI: SE0002998 (26.64 %), SE0003014 (24.21 %), SE0003015 (8.55 %)

    Carbon monoxide
    ISO: SE0002998 (27.11 %), SE0003000 (20.8 %), SE0003001 (20.8 %), SE0003005 (4.79 %), SE003006 (4.79 %), SE0003014 (5.69 %)
    HCI: SE0003000 (24.68 %), SE0003001 (24.68 %), SE0003012 (25.19 %), SE0003015 (23.44 %)

    The apparent increase of HPHC yields can result from the pyrolysis of ingredients added or increased in the new product. Inhalation exposures to the pyrolysis products of many of these ingredients in top and casing flavors, cigarette paper and seam adhesives have been associated

with toxicological effects relevant to human health, including adverse effects on the respiratory system. You cited one published literature (Coggins, et al., 2013) to support that the ingredient changes in adhesives do not cause the new product to raise different questions of public health. However, you did not provide a rationale explaining how the information generated using the experimental cigarettes in the cited study can be extrapolated to the specific new and predicate product. You needed to provide scientific evidence that the addition or increase of ingredients in the new product relative to the predicate product and the combustion products do not cause the new product to raise different questions of public health.

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 SE0002998, SE0003000, SE0003001, SE0003005, SE0003006, SE0003012, SE0003014, SE0003015, SE0003020, SE0003021, SE0003022, SE0003023.

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

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

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/contactus/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 SE0002998, SE0003000, SE0003001, SE0003005, SE0003006, SE0003012, SE0003014, SE0003015, SE0003020, SE0003021, SE0003022, SE0003023.** 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 Report.

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

If you have any questions, please contact Jaime Golwalla, Regulatory Health Project Manager, at (301) 796 - 2878 or Jaime.Golwalla@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.08.23 13:08:01 -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:	Joseph Anderson d/b/a Smokin Joes
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0002998
Product Name:[2]	Smokin Joes Menthol Gold King Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.8 mm
Ventilation:	6 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Menthol Light King Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

[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:	SE0003000
Product Name:[2]	Smokin Joes Menthol King Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Menthol King Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003001
Product Name:[2]	Smokin Joes Menthol King Size Box Fire Safe
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Menthol King Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003005
Product Name:[2]	Smokin Joes Red 100 Size Box Fire Safe
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Full Flavor 100's Box
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003006
Product Name:[2]	Smokin Joes Red 100 Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Full Flavor 100's Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003012
Product Name:[2]	Smokin Joes Natural Menthol 100 Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	99 mm
Diameter:[3]	7.8 mm
Ventilation:	4 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Menthol 100's Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	99 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003014
Product Name:[2]	Smokin Joes Natural Menthol King Size Box Fire Safe
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Menthol King Box
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003015
Product Name:[2]	Smokin Joes Natural Menthol Gold 100 Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	99 mm
Diameter:[3]	7.8 mm
Ventilation:	4 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Menthol Light 100's Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	99 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003020
Product Name:[2]	Smokin Joes Natural Purple 100 Size Box Fire Safe
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Full Flavor 100's Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003021
Product Name:[2]	Smokin Joes Natural Purple 100 Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.8 mm
Ventilation:	2 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Full Flavor 100's Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003022
Product Name:[2]	Smokin Joes Natural Purple King Size Box Fire Safe
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	84 mm
Diameter:[3]	7.8 mm
Ventilation:	13 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Full Flavor King Box
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	84 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0003023
Product Name:[2]	Smokin Joes Natural Purple King Size Soft Pack Fire Safe
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	84 mm
Diameter:[3]	7.8 mm
Ventilation:	13 %
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Smokin Joes Natural Full Flavor King Soft Pack
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	84 mm
Diameter:[3]	7.91 mm
Ventilation:	0 %
Eligibility Status:	Grandfathered