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

July 05, 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): SE0003030

Dear Mr. Scheineson:

We have completed our review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

New Tobacco Product

Date of Submission:	March 21, 2011
Date of Receipt:	March 22, 2011
Product Manufacturer:	Joseph Anderson d/b/a Smokin Joes
Product Name:[1]	Smokin Joes Natural White 100 Size Box Fire Safe
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:	Not provided
Ventilation:	None

We have determined that your SE Report does not establish that the new tobacco product specified above is substantially equivalent to the following predicate tobacco product:

[1] Brand/sub-brand or other commercial name used in commercial distribution.

Predicate Tobacco Product

Product Manufacturer:	Joseph Anderson d/b/a Smokin Joes
Product Name:[2]	Smokin Joes Natural Ultra Light 100's Soft Pack
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	Not provided
Diameter:	7.91 mm
Ventilation:	None

We have described below our basis for this determination.

1. Your SE Report does not include all the design parameters necessary to fully characterize the new and predicate tobacco products. To adequately characterize the products, FDA needed **upper and lower range limits** for *all* the following cigarette design parameters for the new and predicate tobacco products:

    a. Filter length (mm)
    b. Filter total denier (g/9000 m)[3]
    c. Filter denier per filament (dpf)[3]

    Additionally, FDA needed **upper and lower range limits** for *all* the following cigarette design parameters for the new tobacco product:

    d. Cigarette diameter (mm)
    e. Tobacco rod density (g/cm^3)
    f. Tobacco filler mass (mg)

    For the new tobacco product, you stated that the data provided for the tobacco filler mass and tobacco rod density was "based on data from scientific consultant's physical analysis of samples of the product." Thus, the data provided reflected a sample of the actual manufacturing outcome, not the target of the process, and cannot be used to characterize the design parameters. Furthermore, the target specification provided for the tobacco filler mass of the predicate tobacco products was listed as an approximation. FDA needed an exact **target specification and upper and lower range limits** for *all* the following cigarette design parameters:

    g. Tobacco filler mass (mg) [new and predicate]
    h. Tobacco rod density (g/cm^3) [new tobacco product only]

    Without this information, FDA was unable to determine that any differences in the new tobacco product do not cause it to raise different questions of public health.

2. Your SE Report includes some of the design parameter specifications but does not include data confirming that specifications were met. FDA needed **test data (i.e., measured values of design**

[2] Brand/sub-brand or other commercial name used in commercial distribution.
[3] Note that denier per filament and total denier are needed because filter efficiency (%) was not provided.

parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for *all* the following cigarette design parameters for the new and predicate tobacco products:

a. Overall cigarette draw resistance (mm H_2O)
b. Tobacco filler mass (mg)
c. Tobacco moisture (%)
d. Filter ventilation (%)
e. Filter density (g/cm^3)

You also submitted documentation from the cigarette paper suppliers and filter tow suppliers as test data. However, the documentation lacked complete information to indicate that the target specifications were met for the cigarette paper base paper basis weight, cigarette paper base paper porosity, cigarette paper band porosity, filter total denier, or denier per filament. Furthermore, the documentation provided for the predicate tobacco products does not appear to be for the tow used in your product. FDA needed 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* the following cigarette design parameters for the predicate and new tobacco products, unless otherwise noted:

f. Cigarette paper base paper basis weight (g/m^2)
g. Cigarette paper base paper porosity (CU)
h. Cigarette paper band porosity (CU) [new tobacco product only]
i. Filter denier per filament (dpf)
j. Filter total denier (g/9000m)

FDA indicated that a certificate of analysis from the material supplier may have satisfied components of this deficiency. We stated that the COAs 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. The COA was to be a complete, unaltered COA from the material supplier, and it should have been clear which COA should be used for which product. However, the COAs that were received did not provide this information. Without this information, FDA cannot make a determination that the new tobacco product does not raise different questions of public health.

3. Your SE Report indicates that the new tobacco product may have multiple cigarette paper base paper materials because, as you stated, "it may be necessary to switch between the current [supplier's] product and the alternate [supplier's] product." However, in accordance with section 910(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), each product modification, including use of an alternate material, constitutes a new tobacco product. For FDA to determine if a listed material is an alternate material (due to differences in composition), we needed the following information for the new and predicate tobacco products, which consisted of a single combination of cigarette paper base paper materials:

a. Every unique material combination in the predicate tobacco product that you compared to the new tobacco product in accordance with Section 910(a)(2)(B) of the FD&C Act.
b. Every unique material combination in the new tobacco product under Section 905(j)(2) of the FD&C Act. Each specific combination of materials is considered a single new tobacco product and evaluated individually in accordance with Section 910(a)(2)(B) of the FD&C Act.

Without this information, FDA cannot make a determination that the new tobacco product does not raise different questions of public health.

4. Your SE Report contains inconsistent information between the original submission and your June 24, 2015 amendment. You do not state if the information provided in the amendment supersedes the information provided in the original submission. FDA needed confirmation of the target specifications and rationale for the discrepancies for each of the following design parameters:

    a. Filter length (mm) [predicate tobacco products only]
    b. Tobacco rod length [predicate tobacco products only]
    c. Filter weight [new and predicate tobacco products]
    d. Cigarette paper weight [new and predicate tobacco products]
    e. Tipping paper weight [new and predicate tobacco products]
    f. Cigarette paper seam adhesive weight [new and predicate tobacco products]
    g. Tipping adhesive weight [new and predicate tobacco products]

    Furthermore, the upper and lower range limit information you provided in your June 24, 2015 amendment was based on the corresponding target specification. Due to inconsistencies in the target specifications, it is not clear if the upper and lower range limits were intended to be used for any target specification value or only for the target specification provided in the June 24, 2015 amendment. Therefore, FDA needed confirmation of the target specifications and upper and lower range limits and rationale for the discrepancies for each of the following design parameters:

    h. Cigarette length (mm) [predicate tobacco products only]
    i. Cigarette diameter (mm) [new tobacco products only]
    j. Cigarette paper base paper porosity (CU) [new and predicate tobacco products]

    Additionally, in your June 24, 2015 amendment, tipping paper 'length' is identified as 27 mm while tipping paper 'width' is different. If the tipping paper is 27 mm, as reported in the amendment, you should have provided a rationale as to why the tipping paper is not long enough to completely cover the filter. If you intended to report the tipping paper 'width' as the 'length' in the June 24, 2015 amendment, there are discrepancies between the tipping paper length target values provided in the amendment and the original submission. Therefore, FDA needed confirmation of the target specifications and upper and lower range limits and a rationale for the discrepancies in the tipping paper length of the new and predicate tobacco product. Without this information, FDA cannot make a determination that the new tobacco product does not raise different questions of public health.

5. Your SE Report provided information on the design parameters; however, some of the design parameters included information that need additional clarification for FDA to fully characterize the new and predicate tobacco products:

    a. For the new and predicate tobacco products, the tobacco moisture upper and lower range limits are reported as "±1%." Given that the target specification is also reported as a percent, it is unclear if the upper and lower range limits were taken to be ±1% of the target specification or if the applicant intended to report the range limits as 1% higher and lower than the target specification.
    b. For the new tobacco product, band spacing and band width information is incomplete. You provide a data label that lists both design parameters; however, only one target

specification and one set of upper and lower range limits is provided. It is unclear which design parameter is associated with the data.

c. For the predicate tobacco product, the range limit for filter density are 0.25 g/cm^3 higher and lower than the target specification. However, this would lead to a negative lower range limit value, which is not achievable.
d. For the new tobacco product, "Band Porosity (CU)/Band Diffusion (cm/s)" target specification is listed using "cm/s" as the unit of measure. Based on the data label, this implied that you reported the cigarette paper band diffusion. Diffusivity and porosity are not interchangeable. Furthermore, your SE Report provided the new tobacco product cigarette paper band porosity using "g" as the unit of measure. This is not an accepted porosity unit of measure. FDA needed to understand your intention for these values.

Without the necessary clarification to these points, FDA cannot make a determination that the new tobacco product does not raise different questions of public health.

6. Your SE Report states that the new and predicate tobacco product filter ventilation target specifications as <1%. This is not an exact value and prevents the complete characterization of the new and predicate tobacco products. Furthermore, in the June 24, 2015 amendment, you report the "Tip Ventilation Rate" for the new and predicate tobacco products. FDA was unclear if "Tip Ventilation Rate" was intended to represent filter ventilation. In order to fully characterize the filter ventilation (%) and overall draw resistance (mm H2O), FDA needed target specifications and range limits for the new and predicate tobacco products. Without this information, FDA cannot make a determination that the new tobacco product does not raise different questions of public Health.

7. Your SE Report included partial filter pressure drop test data for the new tobacco product. However, the information you provided is not complete and, therefore, cannot be used to confirm that the target specifications have been met. Because you did not provide quantitative acceptance criteria for the test data, the upper and lower range limits were used to determine if the test data met the specifications. Some of the test data points fell outside of the upper and lower range limits of these parameters, indicating that the range limits may not be representative of the final product. FDA needed to understand the effects of data excursions upon the performance of the new tobacco product, how you address data that falls outside of the range limits, and how future product specifications will be prevented from falling outside of range limits. Without this information, FDA was unable to determine that any changes to the new tobacco product do not cause it to raise different questions of public health.

8. Your SE Report provides a detailed list of ingredients for the new and predicate tobacco products. However, your SE Report also contains several discrepancies. For example:

    a. Ingredient quantities given in the SE Report do not match ingredient quantities given in the June 2015 amendment, and it is unclear if the information in the amendment is supposed to replace or complement information presented in the original SE Report.
    b. All provided ingredient quantities are target quantities, often without upper or lower range limits.
    c. Some ingredient quantities are represented by shaded cells in the Excel spreadsheets, with no explanation of the intended meaning of a shaded cell.
    d. The provided total tobacco quantity for the predicate tobacco product does not match the calculated sum of the provided individual tobacco type quantities.

e. Subcomponent ingredient quantities are in percentages, and in some cases percentage ranges, instead of individual target or measured values.
f. Ingredient quantities in most adhesive components in the new and predicate tobacco products are in ranges, with no target quantity provided.

FDA needed clarification on these points to evaluate the new and predicate tobacco products and determine if the new tobacco product raises different questions of public health. Without this information, FDA was unable to determine that any differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

9. Your SE Report provides HPHC data for the new and "present day predicate" (remanufactured predicate), including measured values for TNCO, acetaldehyde, benzene, and B[a]P, under both ISO and CI smoking regimens. You claim the use of the remanufactured predicate tobacco product is necessary because the grandfathered product is not currently available and state that the remanufactured predicate tobacco product is made with the same materials and components as the grandfathered product, as marketed on February 15, 2007. However, you did not provide sufficient documentation or clear explanations to support this claim. Without sufficient documentation or a clear explanation, FDA cannot sufficiently evaluate if the remanufactured predicate tobacco product is consistent with the product design and composition of the original grandfathered product. Additionally, per your July 2017 amendment, different samples were stored at different temperatures for different lengths of time, with no rationale for why the different storage conditions would not affect results of HPHC testing. You also provided the names of the internal lab methods used, but with no additional description or explanation of the method procedures. To evaluate the validity of the HPHC data, FDA needed a clear statement or sufficient documentation showing that your remanufactured predicate tobacco product is consistent with the product design and composition (tobacco, ingredients other than tobacco, and materials) of the grandfathered product, and thus, the HPHC yields from the remanufactured predicate tobacco product are reflective of the HPHC yields from the grandfathered product. FDA also needed a detailed description of all methods used, validation reports for all methods used, and storage conditions, including temperature and length of time, for all samples tested. Without this information, FDA was unable to determine that any differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

10. Your SE Report provides HPHC data for the new and remanufactured predicate tobacco product, including measured values for nicotine, under both ISO and CI smoking regimens. However, the data provided shows the new tobacco product to have higher mainstream smoke yields of nicotine when compared to the remanufactured predicate tobacco product. You have not provided scientific evidence or rationale for why the higher nicotine yields do not raise different questions of public health. Nicotine is a known addictive chemical in tobacco products, so FDA needed this information. Without this evidence and rationale, FDA was unable to determine that the differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

11. Your SE Report provides HPHC data for the new and remanufactured predicate tobacco products, including measured values for TNCO, acetaldehyde, benzene, and B[a]P, under both ISO and CI smoking regimens. However, your Reports lack additional HPHC data FDA needs, because of significant differences in tobacco blend casing flavor ingredients in the new tobacco product compared to the predicate tobacco product. For example, (b)(4) [redacted] are only present in the new tobacco product. Higher quantities of

combusted sugars may raise the mainstream smoke yields of formaldehyde, acrolein, and benzene. Higher quantities of combusted humectants like (b) (4) may raise mainstream smoke yields of acetaldehyde, acrolein, and formaldehyde. These differences between the new and predicate tobacco products may cause the new tobacco product to raise different questions of public health. To evaluate all ingredient differences between the new and predicate tobacco products, FDA needed scientific evidence and rationale to address why any differences did not cause the new tobacco products to raise different questions of public health. One way that such data could have been provided was to measure mainstream smoke yields for the following HPHCs:

a. Acrolein
b. Formaldehyde

If the mainstream smoke yields of acrolein or formaldehyde were higher for the new tobacco product, relative to the predicate tobacco product, FDA would need adequate scientific evidence and rationale as to why the higher HPHC yields did not cause the new tobacco product to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would have best characterized the delivery of constituents from these products. FDA suggested that appropriate measures be taken to minimize data variability and systematic bias. The suggested measures included, but were 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 a similar timeframe. In addition to the smoke data, FDA needed the following information about HPHC testing to fully evaluate the differences in HPHC quantities between the new and predicate tobacco products:

c. Reference product datasets (e.g., 1R6F)
d. Quantitative test protocols and method used
e. Validation reports for methods used
f. Testing laboratory and their accreditation(s)
g. Length of time between date(s) of manufacture and date(s) of testing
h. Number of replicates
i. Standard deviation(s)
j. Complete data sets
k. A summary of the results for all testing performed
l. Storage conditions prior to initiating testing

Without this information, FDA was unable to determine that any differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

12. Your SE Report indicates an apparent increase in carbon monoxide, acetaldehyde relative to the remanufactured predicate tobacco product. The increases in HPHC levels may reflect the overall consequences of the differences in characteristics between the new and predicate tobacco products, such as changes in tobacco blends, cigarette papers, adhesives, and flavor ingredients. Increases in smoke yields of this HPHC in the new tobacco product as compared to their predicate tobacco product could result in increased HPHC exposures for users of the new tobacco product. The increased HPHCs include carcinogen (acetaldehyde), cardiovascular, reproductive, and development toxicants (CO). FDA needed sufficient evidence to demonstrate that the increased acetaldehyde level in the new tobacco product does not cause the new tobacco product to raise different questions of public health. Without this information, FDA was

unable to determine that differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

13. Your SE Report specifies that the defoamers and preservatives added to the seam adhesive in the new tobacco products are different from the predicate tobacco product. You indicated that the preservatives added to the new tobacco product are a proprietary mixture, and limited information was provided regarding the identity and quantities of the subcomponents. The opinion by Perfetti and cited reference by Coggins et al., (2013) are insufficient in providing product-specific supporting evidence to demonstrate that the differences in ingredients between the new and predicate tobacco products do not cause this new tobacco product to raise different questions of public health. To conduct a comprehensive toxicological evaluation, the detailed list of uniquely identifying information (e.g., grade/purity and ingredient quantities) of the compounds present in these complex ingredients is needed. Since the new tobacco product is a combustible cigarette, the toxicological consequences of exposure to the individual components (and their pyrolysis products) *via* the inhalation route needed to be addressed. Even if the individual ingredients are not available, FDA needed scientific evidence and rationale for why the addition of these ingredients does not cause the new tobacco product to raise different questions of public health when these ingredients and/or ingredient byproducts are taken in *via* the inhalation route. Without this information, FDA was unable to determine that any differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

You have failed to provide sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that this new tobacco product is not substantially equivalent to an appropriate predicate tobacco product. Upon issuance of this order, your tobacco product is 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 this misbranded and adulterated product is not further distributed, imported, sold, marketed, or promoted in the United States by others. Your plan should include information sufficient to distinguish this misbranded and adulterated product 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 SE0003030

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)[4] 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/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 SE0003030**. 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.

In order to legally market the new product described in this application, it 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.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.07.05 06:48:44 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

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