



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

October 25, 2013

**NOT SUBSTANTIALLY EQUIVALENT**

FDA Submission Tracking Number (STN): (b) (4)

(b) (4)

Dear (b) (4) :

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:

<b>Applicant:</b>	(b) (4)
<b>Tobacco Product Name<sup>1</sup>:</b>	(b) (4)
<b>Tobacco Product Category:</b>	Cigarette
<b>Tobacco Product Sub-Category:</b>	Filtered (combustion)
<b>Package Size:</b>	20 cigarettes per pack
<b>Package Type:</b>	(b) (4)

We have completed the review of your SE Report and have determined that it does not establish that the product specified above is substantially equivalent to the predicate tobacco product, (b) (4). We have described below our key basis for this determination.

The following deficiencies demonstrate that the new tobacco product is not substantially equivalent to the predicate tobacco product:

1. The data submitted in your SE Report indicates that the mainstream smoke from the new tobacco product has significantly higher yields of (b) (4) (b) (4) than the mainstream smoke from the predicate tobacco product under both the (b) (4). Assuming the submitted data is accurate (see other comments in this letter), these differences cause the new tobacco product to raise different questions of

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

public health. Furthermore, these results may indicate that yields of other nitrosamines and (b) (4) are also increased for the new tobacco product relative to the predicate tobacco product but you did not submit data on the levels of these additional constituents. If the yields of other nitrosamines or (b) (4) are higher in the new tobacco product than the predicate tobacco product, your SE Report would need to explain why the new tobacco product does not raise different questions of public health.

2. The health information summary included in your SE Report is intended to give an “accurate, complete, not false or misleading summary...” of the health effects of the product to the public (section 910(a)(4) of the FD&C Act). However, your SE Report states that the data provided (b) (4). Therefore, your health information summary does not comply with section 910(a)(4) of the FD&C Act.

In addition, the following deficiencies prevent a determination that the new tobacco product is substantially equivalent to the predicate tobacco product:

3. Your SE Report provided HPHC quantities in mainstream smoke produced by a (b) (4), along with specifications for this cigarette. The (b) (4) was analyzed alongside the new and predicate tobacco products. The quantities of tar and carbon monoxide produced by (b) (4) 20 percent lower than the quantities listed in the specifications. Your SE Report lacks information to demonstrate that these quantities are acceptable (e.g., control chart data, control limits, acceptance criteria). This information is necessary because, if the results from (b) (4) are not acceptable, then the HPHC results for the new and predicate tobacco products are not acceptable.
4. Your SE Report listed the unit of measure for (b) (4) per cigarette. The unit of measure for these HPHCs was reported as (b) (4) per cigarette in (b) (4). Your SE Report did not clarify this discrepancy.
5. Your SE Report included HPHC data for the new and predicate tobacco products as well as data for (b) (4) products. Your SE Report states that the (b) (4) products are the same as the new and predicate tobacco products that are subject of your SE Report, (b) (4) than the new and predicate tobacco products. Your SE Report also includes design parameters for the (b) (4) products and the new and predicate tobacco products. Your SE Report lacks the following information that is needed for FDA to fully evaluate the submitted HPHC data and determine whether the new tobacco product is substantially equivalent to the predicate tobacco products:
  - a. The name of the (b) (4) predicate product identified in the (b) (4) is not consistent throughout your report, as (b) (4) are used to describe the (b) (4) predicate product

in your SE Report. The HPHC data in your SE Report does not clearly and consistently identify the predicate tobacco product that is associated with the data as the (b) (4) predicate product referenced in the (b) (4)

- b. Your SE Report describes the (b) (4) new and predicate products tested in the (b) (4) as “the same” as the new and predicate tobacco products that are subject of your SE Report. As confirmation that the (b) (4) products are identical to the new and predicate tobacco product, your SE Report included side-by-side comparison of the design parameters for (b) (4) products and those for the new and predicate tobacco products. The side-by-side comparison contains conflicting data and inconsistent product names, which prevents confirmation that that the design parameters for the (b) (4) products are identical to those for the new and predicate tobacco products.
6. Your SE Report included some design parameters for the new and predicate tobacco products as well as for (b) (4) products. Your SE Report states that the (b) (4) products are the same as the new and predicate tobacco products that are subject of your SE Report, with different product names than the new and predicate tobacco products. Your SE Report lacks the following design parameter information that is needed for FDA to fully evaluate the similarities between the new and predicate tobacco products and the (b) (4) products:
    - a. Your SE Report provided a rationale for increased filter ventilation, filter and other design parameter changes in the new tobacco product compared to the predicate tobacco product. But, your SE Report lacks a side-by-side comparison of the TNCO, filter efficiency, and puff count for the (b) (4) products with those for the new and predicate tobacco products. This information is needed to confirm with the design parameters for the (b) (4) products are identical to those for the new and predicate tobacco products.
    - b. Your SE Report provided (b) (4) mass of the (b) (4) new product and (b) (4) mass of the (b) (4) predicate product. For the (b) (4) new and predicate products, one of the mass values is within and one of the mass values is outside the (b) (4) for the products. Your SE Report did not provide a scientific explanation and rationale for the inconsistencies between the (b) (4) mass in the (b) (4) new and predicate products and the pass/fail criteria for the new and predicate tobacco products that are subject of your SE Report.
  7. Your SE Report did not include cigarette paper base paper porosity test data for the predicate tobacco product. Your SE Report stated that cigarette paper base paper porosity (b) (4) (b) (4) Paper porosity data is needed to understand the similarities and differences in characteristics between the new and

predicate tobacco products. Certificates of analysis (COAs) from the paper supplier for the cigarette paper could provide such data, but COAs were not submitted.

8. Your SE Report provided cigarette paper (b) (4) for the new tobacco product and cigarette paper (b) (4) for the predicate tobacco product. However, your SE Report did not explain the (b) (4), preventing a comparison of these design parameters.

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. Failure to receive the necessary marketing authorization from FDA for this new tobacco product renders it adulterated and misbranded under Sections 902 and 903 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded tobacco product is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action.

If you wish to seek further FDA review of this decision, we suggest that you first request a meeting with the FDA staff who reviewed your submission. If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter, or mail to:

Center for Tobacco Products  
Food and Drug Administration  
Document Control Center, Rm 020J  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for (b) (4)**. In addition, we request that your package identify each basis for the request and contain 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.

**You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii), (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).**

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

If you have any questions, please contact (b) (4)

Sincerely,

Digitally signed by David Ashley -S  
Date: 2013.10.25 07:14:05 -04'00'

David L. Ashley, Ph.D.  
RADM, U.S. Public Health Service  
Director, Office of Science  
Center for Tobacco Products



Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

October 25, 2013

**NOT SUBSTANTIALLY EQUIVALENT**

FDA Submission Tracking Number (STN): (b) (4)

(b) (4)

Dear Mr. (b) (4) :

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:

**Applicant:** (b) (4)  
**Tobacco Product Name<sup>1</sup>:** (b) (4)  
**Tobacco Product Category:** Smokeless  
**Tobacco Product Sub-Category:** Pouched Snus  
**Package Size:** (b) (4)  
**Package Type:** (b) (4)

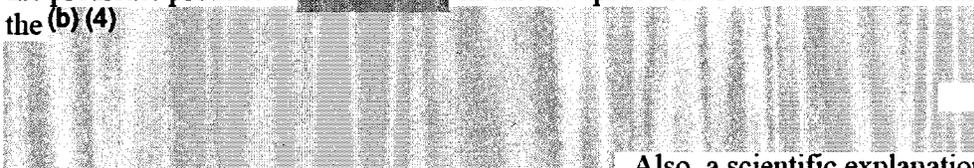
We have completed the review of your SE Report and have determined that it does not establish that the product specified above is substantially equivalent to the predicate tobacco product, (b) (4). We have described below our basis for this determination.

1. Your SE Report lists (b) (4) in the new product. However, your SE Report does not fully characterize these types of tobacco. Information about the origin, grade, curing/processing method, additives used in curing/processing, taste characteristics, and chemical and physical characteristics for each type of tobacco is needed.

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

2. Your SE Report indicates that the new product has substantial decreases in (b) (4) types of tobacco and the (b) (4) as compared to the predicate product. However, you do not explain why substantial changes in the tobacco blend would not cause the new product to raise different questions of public health.
3. Your SE Report provides information about ingredients and quantities used in the new and predicate products. However, your SE Report does not fully characterize the ingredients. Additional information about the grades or purities and suppliers of the ingredients in the new and predicate products is needed.
4. Your SE Report indicates that the quantity of (b) (4) would be (b) (4) to change the (b) (4). Including variance, this difference could be as much as (b) (4). (b) (4) particularly when made within the range of (b) (4) (b) (4) will increase the level of free, more readily absorbed, nicotine. You did not explain why the change would not cause the new tobacco product to raise different questions of public health.
5. Your SE Report provides data listing several harmful and potentially harmful constituents (HPHCs) in snus products manufactured in (b) (4). However, your SE Report does not identify the names of the products tested. In addition, your SE Report includes (b) (4).  
One of the reports includes data for (b) (4). However, these reports do not clearly indicate whether the products tested were the new or predicate products. You have indicated, in teleconferences, that recently measured values for nicotine and other HPHCs are outside of the specified target ranges for these constituents. Further, you noted that measurements were made on new and predicate products that had been manufactured in (b) (4). Reports that are (b) (4) in both the new and predicate products are needed. Additionally, quantitative data showing HPHC levels in the predicate product that (b) (4) on the grandfather date of February 15, 2007, are needed. An explanation for when and why measured HPHC quantities for your new and predicate products are outside specified target values and support explanation with data is omitted. Finally, full test data including specific testing protocols, descriptions of the test methods, acceptance criteria (pass/fail), deviations, complete testing data sets, and testing facility credentials for all testing performed is needed.
6. Your SE Report provides data on tobacco additives, but not ingredients that make up the snus (b) (4). Chemical composition along with the physical properties of the (b) (4) products. Additional information about the ingredients that make up the snus portion (b) (4) is

needed along with a scientific explanation of how these changes do not cause the new tobacco product to raise different questions of public health.

7. Your SE Report includes a picture of the packaging disassembled, a picture of a finished package, packaging dimensions, and artwork for the new product. However, an ingredient list for each of the packaging components needs to be provided for both the new and predicate products (e.g., lid, can, adhesive, label) since the packaging components have been known to affect tobacco products. A list of packaging components/materials for the predicate and new products is needed. If the packaging components/materials are identical for both products, detailed component/material information for the packaging of the new products and a statement that this information is identical to the predicate products must be submitted. If any changes were made to any components or materials of the packaging (e.g., inks, board, adhesives), a side-by-side comparison of the packaging to identify each change must be provided.
8. Your SE Report indicates that the final moisture changes from (b) (4) the predicate product to (b) (4) in the new product. You also indicate that the (b) (4)  


Also, a scientific explanation of how these changes to moisture content do not cause the new tobacco product to raise different questions of public health is needed.
9. The dimensions of the portion, in millimeters, are described as (b) (4) for both the predicate product and the new product. The weight of the paper for the new product is given as (b) (4) per pouch versus (b) (4) for a pouch of the predicate product. A change in the weight per unit of a pouch paper could impact the performance of the snus product. Therefore, verification that these values are accurate, including any corrections that need to be made for accuracy, is needed along with clarification for how the paper weight per pouch changed despite the identical pouch dimensions. Also, the following design parameters for the pouch paper were omitted; porosity, basis weight, caliper, and any other specifications for the pouch material. If changes were made to the pouch design, a scientific explanation of how these changes do not cause the new tobacco product to raise different questions of public health is needed.
10. Your SE Report provides a range for the tobacco particle size from (b) (4) for the new product. However, you do not make the tobacco particle size range for the predicate product clear. Tobacco particle size can play an important role in the delivery profile of the product. A side-by-side comparison of the particle size distribution details for the new and predicate products at the most detailed level that you have available, including testing procedures or control procedures, is needed. A scientific explanation of how these changes do not

cause the new tobacco product to raise different questions of public health was not provided.

11. Your SE Report lacks the appropriate toxicological evidence to demonstrate that the addition of the new flavoring (b) (4) to the new tobacco product does not raise different questions of public health.
12. Your SE Report states that the flavor profile of the new and predicate products are significantly different. You did not submit information describing why you believe these changes would not cause the new product to raise different questions of public health. Information justifying how this flavor difference will not cause the new product to raise different questions of public health (including increased initiation and/or delayed cessation) is needed.<sup>2</sup>
13. Your SE Report includes a health information summary. The summary is not complete in that it fails to address the widely-acknowledged risks of smokeless tobacco products other than nicotine dependence. In addition, it would likely mislead members of the public that might review it. Specifically, statements such as (b) (4) would likely result in consumers believing that this product may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products. Therefore, your health information summary does not comply section 910(a)(4) of the FD&C Act.

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. Failure to receive the necessary marketing authorization from FDA for this new tobacco product renders it adulterated and misbranded under Sections 902 and 903 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded tobacco product is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action.

If you wish to seek further FDA review of this decision, we suggest that you first request a meeting with the FDA staff who reviewed your submission. If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter, or mail to:

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<sup>2</sup> Note that, in the Preliminary Finding letter, the agency requested the information identified in this deficiency. However, the agency has determined that the information identified in this deficiency is now required to demonstrate substantial equivalence.

Center for Tobacco Products  
Food and Drug Administration  
Document Control Center, Rm 020J  
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Rockville, MD 20850-3229

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for (b) (4)**. In addition, we request that your package identify each basis for the request and contain 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.

**You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii), (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).**

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

If you have any questions, please contact (b) (4)

Sincerely,

Digitally signed by David Ashley -S  
Date: 2013.10.25 07:24:33 -04'00'

David L. Ashley, PhD  
RADM, U.S. Public Health Service  
Director, Office of Science  
Center for Tobacco Products



October 30, 2013

**NOT SUBSTANTIALLY EQUIVALENT**

FDA Submission Tracking Number (STN): (b) (4)

(b) (4)

Dear (b) (4) :

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:

**Applicant:** (b) (4)  
**Tobacco Product Name<sup>1</sup>:** (b) (4)  
**Tobacco Product Category:** Smokeless  
**Tobacco Product Sub-Category:** Loose moist snuff  
**Package Size:** (b) (4)  
**Package Type:** (b) (4)

We have completed the review of your SE Report and have determined that it does not establish that the product specified above is substantially equivalent to the predicate tobacco product, (b) (4). We have described below our basis for this determination.

- The SE Report indicates that the new tobacco product contains (b) (4), while the predicate tobacco product does not contain these ingredients. These ingredients have (b) (4) at certain doses. It is possible for (b) (4) in the new tobacco products to have these (b) (4)

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

if the quantity of these ingredients exceeds the acceptable daily intake (ADI). There is no established ADI for (b) (4); however, the ADI for (b) (4) [redacted]. The (b) (4) [redacted]

Based on review of the published literature, it is likely that users of moist snuff will consume several portions in a typical day – estimates range from 6 to 16 dips per day. This level of (b) (4) [redacted] exposure far exceeds the ADI of (b) (4) [redacted] and approaches the (b) (4) [redacted]

[redacted]. In response to the preliminary finding letter, the SE Report states that (b) (4) [redacted]

However, the SE Report does not contain any scientific data, published literature, or a clinical study demonstrating that the quantity of (b) (4) [redacted] in the new tobacco product is sufficiently low enough that it is (b) (4) [redacted] under conditions of actual use. Therefore, the new tobacco product raises 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. Failure to receive the necessary marketing authorization from FDA for this new tobacco product renders it adulterated and misbranded under Sections 902 and 903 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded tobacco product is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action.

If you wish to seek further FDA review of this decision, we suggest that you first request a meeting with the FDA staff who reviewed your submission. If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter, or mail to:

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9200 Corporate Boulevard  
Rockville, MD 20850-3229

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for (b) (4)** [redacted]. In addition, we request that your package identify each basis for the request and contain 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.

**You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii), (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).**

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

If you have any questions, please contact (b) (4)

Sincerely,

Digitally signed by David Ashley -S

Date: 2013.10.30 11:49:55 -04'00'

David L. Ashley, PhD  
RADM, U.S. Public Health Service  
Director, Office of Science  
Center for Tobacco Products



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
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October 30, 2013

**NOT SUBSTANTIALLY EQUIVALENT**

FDA Submission Tracking Number (STN): (b) (4)

(b) (4)

Dear (b) (4) :

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:

**Applicant:** (b) (4)  
**Tobacco Product Name<sup>1</sup>:** (b) (4)  
**Tobacco Product Category:** Smokeless  
**Tobacco Product Sub-Category:** Loose moist snuff  
**Package Size:** (b) (4)  
**Package Type:** (b) (4)

We have completed the review of your SE Report and have determined that it does not establish that the product specified above is substantially equivalent to the predicate tobacco product, (b) (4). We have described below our basis for this determination.

- The SE Report indicates that the new tobacco product contains (b) (4), while the predicate tobacco product does not contain these ingredients. These ingredients have (b) (4) at certain doses. It is possible for (b) (4) in the new tobacco products to have these (b) (4) if the quantity of these ingredients exceeds the acceptable daily intake (ADI).

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

There is no established ADI for (b) (4); however, the ADI for (b) (4)  
The (b) (4)

Based on review of the published literature, it is likely that users of moist snuff will consume several portions in a typical day – estimates range from 6 to 16 dips per day. This level of (b) (4) or (b) (4) exposure far exceeds the ADI of (b) (4) and approaches the (b) (4)

. In response to the preliminary finding letter, the SE Report states tha (b) (4)

However, the SE Report does not contain any scientific data, published literature, or a clinical study demonstrating that the quantity of (b) (4) in the new tobacco product is sufficiently low enough that it is (b) (4) under conditions of actual use. Therefore, the new tobacco product raises 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. Failure to receive the necessary marketing authorization from FDA for this new tobacco product renders it adulterated and misbranded under Sections 902 and 903 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded tobacco product is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action.

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If you have any questions, please contact (b) (4)

Sincerely,

Digitally signed by David Ashley -S

Date: 2013.10.30 11:50:46 -04'00'

David L. Ashley, PhD

RADM, U.S. Public Health Service

Director, Office of Science

Center for Tobacco Products



October 30, 2013

**NOT SUBSTANTIALLY EQUIVALENT**

FDA Submission Tracking Number (STN): (b) (4)

(b) (4)

Dear (b) (4) :

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**Package Type:** (b) (4)

We have completed the review of your SE Report and have determined that it does not establish that the product specified above is substantially equivalent to the predicate tobacco product, (b) (4). We have described below our basis for this determination.

- The SE Report indicates that the new tobacco product contains (b) (4) while the predicate tobacco product does not contain these ingredients. These ingredients have (b) (4) at certain doses. It is possible for (b) (4) in the new tobacco products to have these (b) (4)

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

if the quantity of these ingredients exceeds the acceptable daily intake (ADI). There is no established ADI for (b) (4); however, the ADI for (b) (4). The (b) (4)

Based on review of the published literature, it is likely that users of moist snuff will consume several portions in a typical day – estimates range from 6 to 16 dips per day. This level of (b) (4) or (b) (4) exposure far exceeds the ADI of (b) (4) and approaches the (b) (4)

. In response to the preliminary finding letter, the SE Report states tha (b) (4)

However, the SE Report does not contain any scientific data, published literature, or a clinical study demonstrating that the quantity of (b) (4) in the new tobacco product is sufficiently low enough that it is (b) (4) under conditions of actual use. Therefore, the new tobacco product raises 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. Failure to receive the necessary marketing authorization from FDA for this new tobacco product renders it adulterated and misbranded under Sections 902 and 903 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded tobacco product is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action.

If you wish to seek further FDA review of this decision, we suggest that you first request a meeting with the FDA staff who reviewed your submission. If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter, or mail to:

Center for Tobacco Products  
Food and Drug Administration  
Document Control Center, Rm 020J  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for (b) (4)**. In addition, we request that your package identify each basis for the request and contain 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.

**You may not legally market the new tobacco product described in this SE Report unless**

**(1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii), (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).**

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

If you have any questions, please contact (b) (4)

Sincerely,

Digitally signed by David Ashley -S

Date: 2013.10.30 11:52:05 -04'00'

David L. Ashley, PhD

RADM, U.S. Public Health Service

Director, Office of Science

Center for Tobacco Products