



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

August 28, 2013

NOT SUBSTANTIALLY EQUIVALENT

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 Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	(b) (4)
Tobacco Product Name¹:	(b) (4)
Tobacco Product Category:	Roll-Your-Own
Tobacco Product Sub-Category:	Filtered Cigarette Tubes
Package Size:	200 Tubes
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 (b) (4) determination.

1. Your SE Report did not provide full identification of your predicate tobacco product (i.e., how the predicate product is uniquely identified for a consumer such as brand, subbrand, size, quantity, and packaging).

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

2. Your SE Report did not provide an adequate summary of health information (Section 910(a)(4)(B) of the FD&C Act) related to your new tobacco product or a statement that it will be made available upon request (Section 910(a)(4)(A) of the FD&C Act).
3. Your SE Report did not provide a statement of your action to comply with the requirements of section 907 (see section 905(j)(1)(B) of the FD&C Act), including those standards under section 907(a) of the FD&C Act and any promulgated through regulation.
4. Your SE Report did not provide an environmental assessment prepared in accordance with 21 CFR 25.40. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 (21 CFR 25.15(a)) require that "[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion." There are no categorical exclusions in place for tobacco products; therefore, manufacturers submitting applications or reports for any of the three regulatory pathways to legally market a new tobacco product (including reports under section 905(j)) must include environmental assessments as part of their submissions. You should refer to 21 CFR Part 25 for additional information.
5. Your SE Report did not provide information about the composition of the (b) (4) for either the new or predicate product.⁽⁴⁾
6. Your SE Report provided information for some ingredients and additives used in the new and predicate products. However, your SE Report did not include adequate information, such as the purity, grade, and supplier, to fully identify the ingredients and additives.
7. In your SE Report, the new product includes the term (b) (4). However, your SE Report did not contain any composition information indicating how the (b) (4) is created in the product.
8. Your SE Report indicates that the amount of (b) (4) in the new product than the predicate product. Your SE Report did not explain how this (b) (4) does not cause the new product to raise different questions of public health.
9. Your SE Report did not provide information on any design features for the predicate or new products. For purposes of a substantive review, sufficient detail on product design to fully identify the predicate and new products is needed. Your SE Report did not provide a comprehensive description of the predicate and new tobacco products including, but not limited to, the following:
 - a. Total Tube Length (mm);
 - b. Tube Circumference (mm);
 - c. Tube Weight (mg);
 - d. Filter Ventilation (%);

- e. Tipping Paper Length (mm);
- f. Cigarette Paper Porosity (CU);
- g. Plug Wrap Porosity (CU);
- h. Filter Length (mm); and
- i. Filter (Plug) Resistance to Draw (mm H₂O).

Your SE Report did not provide full test data (including test protocols, quantitative acceptance (pass/fail) criteria, data sets and a summary of the results) for all testing performed for each product attribute listed above.

10. Your SE Report did not include information needed in order for the FDA to make a determination as to whether or not the tobacco product you have referenced as a predicate is predicate-eligible (grandfathered status).
 - a. Your SE Report did not include evidence to demonstrate that your predicate tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such evidence may include, but are not limited to, the following:
 - dated copies of advertisements;
 - dated catalog pages;
 - dated promotional material;
 - dated trade publications;
 - dated bills of lading;
 - dated freight bills;
 - dated waybills;
 - dated invoices;
 - dated purchase orders;
 - dated customer receipts;
 - dated manufacturing documents;
 - dated distributor or retailer inventory lists;
 - any other document you believe demonstrates that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007.
 - b. Your SE Report did not provide a statement that the predicate tobacco product was not exclusively in a test market as of February 15, 2007.
 - c. Your SE Report did not specify the predicate tobacco product type (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco) or a brief description of how the predicate tobacco product is used by the consumer.

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 (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

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: 2013.08.28 09:48:52 -04'00'

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



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Applicant: (b) (4)
Tobacco Product Name¹: (b) (4)
Tobacco Product Category: Roll-Your-Own
Tobacco Product Sub-Category: Filtered Cigarette Tubes
Package Size: 200 Tubes
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 (b) (4) determination.

1. Your SE Report did not provide full identification of your predicate tobacco product (i.e., how the predicate product is uniquely identified for a consumer such as brand, subbrand, size, quantity, and packaging).

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

2. Your SE Report did not provide an adequate summary of health information (Section 910(a)(4)(B) of the FD&C Act) related to your new tobacco product or a statement that it will be made available upon request (Section 910(a)(4)(A) of the FD&C Act).
3. Your SE Report did not provide a statement of your action to comply with the requirements of section 907 (see section 905(j)(1)(B) of the FD&C Act), including those standards under section 907(a) of the FD&C Act and any promulgated through regulation.
4. Your SE Report did not provide an environmental assessment prepared in accordance with 21 CFR 25.40. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 (21 CFR 25.15(a)) require that "[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion." There are no categorical exclusions in place for tobacco products; therefore, manufacturers submitting applications or reports for any of the three regulatory pathways to legally market a new tobacco product (including reports under section 905(j)) must include environmental assessments as part of their submissions. You should refer to 21 CFR Part 25 for additional information.
5. Your SE Report did not provide information about the composition of the (b) (4) for either the new or predicate product.⁽⁴⁾
6. Your SE Report provided information for some ingredients and additives used in the new and predicate products. However, your SE Report did not include adequate information, such as the purity, grade, and supplier, to fully identify the ingredients and additives.
7. In your SE Report, the new product includes the term (b) (4). However, your SE Report did not contain any composition information indicating how the (b) (4) is created in the product.
8. Your SE Report indicates that the amount of (b) (4) in the new product than the predicate product. Your SE Report did not explain how this (b) (4) does not cause the new product to raise different questions of public health.
9. Your SE Report did not provide information on any design features for the predicate or new products. For purposes of a substantive review, sufficient detail on product design to fully identify the predicate and new products is needed. Your SE Report did not provide a comprehensive description of the predicate and new tobacco products including, but not limited to, the following:
 - a. Total Tube Length (mm);
 - b. Tube Circumference (mm);
 - c. Tube Weight (mg);
 - d. Filter Ventilation (%);

- e. Tipping Paper Length (mm);
- f. Cigarette Paper Porosity (CU);
- g. Plug Wrap Porosity (CU);
- h. Filter Length (mm); and
- i. Filter (Plug) Resistance to Draw (mm H₂O).

Your SE Report did not provide full test data (including test protocols, quantitative acceptance (pass/fail) criteria, data sets and a summary of the results) for all testing performed for each product attribute listed above.

10. Your SE Report did not include information needed in order for the FDA to make a determination as to whether or not the tobacco product you have referenced as a predicate is predicate-eligible (grandfathered status).
 - a. Your SE Report did not include evidence to demonstrate that your predicate tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such evidence may include, but are not limited to, the following:
 - dated copies of advertisements;
 - dated catalog pages;
 - dated promotional material;
 - dated trade publications;
 - dated bills of lading;
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 - dated waybills;
 - dated invoices;
 - dated purchase orders;
 - dated customer receipts;
 - dated manufacturing documents;
 - dated distributor or retailer inventory lists;
 - any other document you believe demonstrates that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007.
 - b. Your SE Report did not provide a statement that the predicate tobacco product was not exclusively in a test market as of February 15, 2007.
 - c. Your SE Report did not specify the predicate tobacco product type (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco) or a brief description of how the tobacco product is used by the consumer.

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 (www.fda.gov/esg) using eSubmitter, or mail to:

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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: 2013.08.28 09:47:20 -04'00'

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



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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 Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	(b) (4)
Tobacco Product Name¹:	(b) (4)
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Tobacco
Package Size:	1-1.5 oz
Package Type:	Not Provided

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 provides information about tobacco and about ingredients added to tobacco in the new product. However, your SE Report does not include sufficient detail about the tobacco composition and ingredients in the predicate product. The quantities of the tobacco blends (b) (4) and quantities of the ingredients (b) (4) to the tobacco (b) (4) for the predicate product are needed. Additionally, the total amount of tobacco (b) (4) per package size between the new and predicate product is needed. Without this information, we could not determine whether the predicate and new products are substantially equivalent. Additionally, the information provided for

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

tobacco does not include sufficient detail to fully identify the composition of the predicate and new tobacco used in the predicate and new products. This is the information that you rely on to ensure that the tobacco used in the predicate and new products address variations in growing conditions. For example, if you use a tobacco grading system, it would have been helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the predicate and new products. Lastly, this ingredient and additive information is needed for all packaging material.

2. Your SE Report does not include any Harmful and Potentially Harmful Constituents (HPHC) quantities in the predicate or new product. This information is necessary to determine whether the two products are substantially equivalent. Minimally, the following HPHCs in the filler of the predicate and new products were needed:
 - a. Nicotine (total)
 - b. Total TSNAs
 - c. NNN
 - d. NNK

The following information about HPHC testing was also needed so that we could have fully evaluated the differences in HPHC quantities in the predicate and new products:

- e. Quantitative methods used
- f. Testing laboratory or laboratories
- g. Length of time between date(s) of manufacture and date(s) of testing
- h. Storage conditions prior to initiating testing

In addition, full test data (including test protocols, any deviations from test protocols, quantitative acceptance (pass/fail) criteria, and complete data sets) is needed for all testing performed.

3. Your SE Report does not provide enough information to evaluate the design features for the predicate or new product. For example, it is not clear if the reported (b) (4) (b) (4). It also is not clear how the tobacco (b) (4) (b) (4). In addition, full test data (including test protocols, any deviations from test protocols, quantitative acceptance (pass/fail) criteria, and complete data sets) is needed for all testing performed.
4. Your SE Report lists the net weight of the new product package as (b) (4) while the predicate package weight is (b) (4). This (b) (4) appears to indicate that there are (b) (4) of the new product included in this SE Report. Confirmation regarding the number of (b) (4) of your new product is necessary. If this is not the case, the actual package size of your new product and a rationale for including the (b) (4) in your SE Report is necessary.

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 (www.fda.gov/esg) using eSubmitter, or mail to:

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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).

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

Sincerely,

Digitally signed by David Ashley -S
Date: 2013.08.28 09:49:49 -04'00'

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



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- Applicant:** (b) (4)
- Tobacco Product Name¹:** (b) (4)
- Tobacco Product Category:** Roll-Your-Own
- Tobacco Product Sub-Category:** Filtered Cigarette Tubes
- Package Size:** 200 Tubes
- 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 (b) (4) determination.

1. Your SE Report did not provide full identification of your predicate tobacco product (i.e., how the predicate product is uniquely identified for a consumer such as brand, subbrand, size, quantity, and packaging).

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

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David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
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