



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

June 25, 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 Name<sup>1</sup>:** (b) (4)
- Tobacco Product Category:** Cigarette
- Tobacco Product Sub-Category:** Filtered Conventional Cigarette
- Package Size:** 20 cigarettes
- 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 provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, the information provided does not include sufficient detail to fully identify the composition of the predicate and new tobacco products.
2. Your SE Report does not identify any other type of tobacco other than (b) (4). (b) (4) This level of detail does not fully identify the tobacco used in the new and predicate tobacco products. Furthermore, your SE Report states that both the new and predicate tobacco products contain (b) (4) tobacco at an (b) (4) (b) (4). This amount of tobacco needs confirmation

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

because it is substantially (b) (4) than what is contained within other brands of cigarette (700 - 900 mg/cigarette).

3. Your SE Report lists many ingredients as present in (b) (4) quantities. This appears to be incorrect because the reported values for some ingredient quantities are (b) (4)
4. Your SE Report lists many ingredients in terms of (b) (4). However, it is not clear what the total refers to. For example, the quantity of (b) (4) is listed as (b) (4). Does the (b) (4) refer to the amount added to tobacco? Your SE Reports also lists many of the ingredients (b) (4) as (b) (4) but needs to list actual quantities.
5. Your SE Report does not provide any information on the HPHCs present in the smoke or filler of new or predicate products. Minimally, your SE Report must provide data comparing the levels of tar, nicotine, and carbon monoxide in the mainstream smoke of the predicate and new tobacco products.
6. Your SE Report includes design parameters for the predicate and new tobacco products. However, your SE Report does not provide sufficient detail on product design to fully identify the predicate and new tobacco products. Your SE Report did not provide an adequately comprehensive description of the predicate and new tobacco products including, but not limited to, lacking the following:
  - a. Graphical representation of the cigarette (including the direction of fade on the tipping to indicate the color on the mouth end);
  - b. Cigarette Weight (mg);
  - c. Cigarette Resistance to Draw (mm H<sub>2</sub>O);
  - d. Puff Count;
  - e. Burn Rates (s);
  - f. Tobacco Filler oven volatiles (OV) or moisture (%);
  - g. Tipping Paper Ventilation (%);
  - h. Tipping Paper Length (mm);
  - i. Filter Length (mm);
  - j. Filter Efficiency (%) - If no filter efficiency data is available for the products, please include information sufficient to show that the cigarette filter is unchanged (denier per filament, total denier, etc.);
  - k. Filter (Plug) Pressure Drop (mm H<sub>2</sub>O); and

In addition, verify that the tobacco weight is (b) (4) per stick. 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 design parameter listed above.

7. Your SE Report indicates that there is a change in the (b) (4) (b) (4) for the predicate tobacco product in (b) (4) of your SE Report is described as (b) (4). However, the information needs clarification because the material specification from (b) (4) of your SE Report is (b) (4)

(b) (4) and the paper ingredients in (b) (4) of your SE Report appear to be for a (b) (4).

8. Your SE Report provides a detailed listing of ingredients in (b) (4) that include levels used for the predicate and new tobacco products. The values provided (b) (4) Accurate product specifications are required to perform relevant evaluation of the data.
9. Your SE Report, in (b) (4) (b) (4) (b) (4) These data cannot be interpreted without a listing of the total mass.
10. Your SE Report includes the addition of constituents that are listed in the Hazardous Substances Data Bank with known toxicities. But, your SE Report does not address all such constituents/substances and why these do not raise new issues of public health. These include, but may not be limited to, (b) (4) (b) (4) Also, it is not clear why the increase of (b) (4) does not cause the new product to raise different questions of public health.
11. The scientific literature shows that (b) (4) influences the way individuals perceive products, including tobacco products. Research shows that (b) (4) influences consumer perceptions of harm, flavor and taste of cigarettes, which in turn may influence the likelihood of product use and initiation of cigarette smoking. However, your SE Report (b) (4) (b) (4)
12. Your SE Report does not include sufficient information needed in order for us to make a determination as to whether or not the tobacco product you have referenced as a predicate is predicate-eligible (grandfathered). The evidence you provided did not indicate specific dates in which commercial marketing of these products occurred in the United States. The information you provided for these submissions consists of a (b) (4) (b) (4) However, this information does not establish that the products were commercially marketed in the United States as of February 15, 2007.

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](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

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)  
(b) (4)

Sincerely,  
(b) (6)

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
Rockville, MD 20850

June 25, 2013

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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: Cigarette
Tobacco Product Sub-Category: Filtered Conventional Cigarette
Package Size: 20 cigarettes
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 provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, the information provided does not include sufficient detail to fully identify the composition of the predicate and new tobacco products.

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

2. Your SE Report does not identify any other type of tobacco other than (b) (4). This level of detail does not fully identify the tobacco used in the new and predicate tobacco products. Furthermore, your SE Report states that both the new and predicate tobacco products contain (b) (4) tobacco at an (b) (4) (b) (4). This amount of tobacco needs confirmation because it is substantially (b) (4) than what is contained within other brands of cigarette (700 - 900 mg/cigarette).
3. Your SE Report lists many ingredients as present in (b) (4) quantities. This appears to be incorrect because the reported values for some ingredient quantities are (b) (4) (b) (4).
4. Your SE Report lists many ingredients in terms of (b) (4). However, it is not clear what the total refers to. For example, the quantity of (b) (4) is listed as (b) (4). Does the (b) (4) refer to the amount added to tobacco? Your SE Reports also lists many of the ingredients (b) (4) as (b) (4) but needs to list actual quantities.
5. Your SE Report does not provide any information on the HPHCs present in the smoke or filler of new or predicate products. Minimally, your SE Report must provide data comparing the levels of tar, nicotine, and carbon monoxide in the mainstream smoke of the predicate and new tobacco products.
6. Your SE Report includes design parameters for the predicate and new tobacco products. However, your SE Report does not provide sufficient detail on product design to fully identify the predicate and new tobacco products. Your SE Report did not provide an adequate description of the predicate and new tobacco products including, but not limited to, lacking the following:
  - a. Graphical representation of the cigarette (including the direction of fade on the tipping to indicate the color on the mouth end);
  - b. Cigarette Weight (mg);
  - c. Cigarette Resistance to Draw (mm H<sub>2</sub>O);
  - d. Puff Count;
  - e. Burn Rates (s);
  - f. Tobacco Filler oven volatiles (OV) or moisture (%);
  - g. Tipping Paper Ventilation (%);
  - h. Tipping Paper Length (mm);
  - i. Filter Length (mm);
  - j. Filter Efficiency (%) - If no filter efficiency data is available for the products, please include information sufficient to show that the cigarette filter is unchanged (denier per filament, total denier, etc.);
  - k. Filter (Plug) Pressure Drop (mm H<sub>2</sub>O); and

In addition, verify that the tobacco weight is (b) (4) per stick. 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 design parameter listed above.

- (b) (4)
7. Your SE Report indicates that there is a change in the (b) (4) for the predicate tobacco product in (b) (4) of your SE Report is described as (b) (4). However, the information needs clarification because the material specification from (b) (4) of your SE Report is (b) (4) and the paper ingredients in (b) (4) of your SE Report appear to be for (b) (4).
  8. Your SE Report provides a detailed listing of ingredients in (b) (4) that include levels used for the predicate and new tobacco products. The values provided (b) (4) (b) (4) Accurate product specifications are required to perform relevant evaluation of the data.
  9. Your SE Report, in (b) (4) (b) (4) (b) (4) These data cannot be interpreted without a listing of the total mass.
  10. Your SE Report indicates that a change was made to the cigarette paper. However, it is unclear whether the new product uses cigarette paper designed to be (b) (4) (b) (4) Identify whether the new product uses (b) (4) Provide the following details on the design for the cigarette paper on the both the new and the predicate product, including any differences between the papers used:
    - a. Cigarette Paper Base Paper Porosity (CU);
    - b. Cigarette Paper Band Porosity (CU);
    - c. Cigarette Paper Band Width (mm); and
    - d. Cigarette Paper Band Spacing (mm)

For each of these parameters, provide full test data (including test protocols, quantitative acceptance (pass/fail) criteria

11. Your SE Report includes the addition of constituents that are listed in the Hazardous Substances Data Bank with known toxicities. But, your SE Report does not address all such constituents/substances and why these do not raise new issues of public health. These include, but may not be limited to, (b) (4) (b) (4) Also, it is not clear why the increase of (b) (4) does not cause the new product to raise different questions of public health.
12. The scientific literature shows that (b) (4) influences the way individuals perceive products, including tobacco products. Research shows that (b) (4) influences consumer perceptions of harm, flavor and taste of cigarettes, which in turn may influence the likelihood of product use and initiation of cigarette smoking. However, your SE Report (b) (4) (b) (4)
13. Your SE Report does not include sufficient information needed in order for us to make a determination as to whether or not the tobacco product you have referenced as a predicate is predicate-eligible (grandfathered). The evidence you provided did not indicate specific

dates in which commercial marketing of these products occurred in the United States. The information you provided for these submissions consists of a presentation on (b) (4)  
(b) (4)

(b) (4) However, this information does not establish that the products were commercially marketed in the United States as of February 15, 2007.

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

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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).**



Page 5, (b) (4)

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)  
(b) (4)

Sincerely,  
(b) (6)

David L. Ashley, PhD  
RADM, U.S. Public Health Service  
Director, Office of Science  
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Submission Tracking Number (STN): (b) (4)

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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: Cigarette
Tobacco Product Sub-Category: Filtered Conventional Cigarette
Package Size: 20 cigarettes
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 provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, the information provided does not include sufficient detail to fully identify the composition of the predicate and new tobacco products.
2. Your SE Report does not identify any other type of tobacco other than (b) (4) (b) (4) This level of detail does not fully identify the tobacco used in the new and predicate tobacco products. Furthermore, your SE Report states that both the new and predicate tobacco products contain (b) (4) tobacco at an (b) (4) (b) (4) This amount of tobacco needs confirmation

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

because it is substantially (b) (4) than what is contained within other brands of cigarette (700 - 900 mg/cigarette).

3. Your SE Report lists many ingredients as present in (b) (4). This appears to be incorrect because the reported values for some ingredient quantities are (b) (4).
4. Your SE Report lists many ingredients in terms of (b) (4). However, it is not clear what the total refers to. For example, the quantity of (b) (4) is listed as (b) (4). Does the (b) (4) refer to the amount added to tobacco? Your SE Reports also lists many of the ingredients (b) (4) as (b) (4) but needs to list actual quantities.
5. Your SE Report shows that (b) (4) would be added to the (b) (4) of the new product. The predicate product does not contain any (b) (4). Provide evidence that the addition of (b) (4) to the (b) (4) would not cause the new product to raise different questions of public health.
6. Your SE Report does not provide any information on the HPHCs present in the smoke or filler of new or predicate products. Minimally, your SE Report must provide data comparing the levels of tar, nicotine, and carbon monoxide in the mainstream smoke of the predicate and new tobacco products.
7. Your SE Report includes design parameters for the predicate and new tobacco products. However, your SE Report does not provide sufficient detail on product design to fully identify the predicate and new tobacco products. Your SE Report did not provide an adequate description of the predicate and new tobacco products including, but not limited to, lacking the following:
  - a. Graphical representation of the cigarette (including the direction of fade on the tipping to indicate the color on the mouth end);
  - b. Cigarette Weight (mg);
  - c. Cigarette Resistance to Draw (mm H<sub>2</sub>O);
  - d. Puff Count;
  - e. Burn Rates (s);
  - f. Tobacco Filler oven volatiles (OV) or moisture (%);
  - g. Tipping Paper Ventilation (%);
  - h. Tipping Paper Length (mm);
  - i. Filter Length (mm);
  - j. Filter Efficiency (%) - If no filter efficiency data is available for the products, please include information sufficient to show that the cigarette filter is unchanged (denier per filament, total denier, etc.);
  - k. Filter (Plug) Pressure Drop (mm H<sub>2</sub>O); and

In addition, verify that the tobacco weight is (b) (4) per stick. Your SE Report did not provide full test data (including test protocols, quantitative acceptance (pass/fail))

(b) (4)

criteria, data sets and a summary of the results) for all testing performed for each design parameter listed above.

8. Your SE Report indicates that there is a change in the (b) (4) (b) (4) of your SE Report is described as (b) (4). However, the information needs clarification because the material specification from (b) (4) of your SE Report is (b) (4) and the paper ingredients in (b) (4) of your SE Report appear to be for a (b) (4).
9. Your SE Report provides a detailed listing of ingredients in (b) (4) that include levels used for the predicate and new tobacco products. The values provided (b) (4). Accurate product specifications are required to perform relevant evaluation of the data.
10. Your SE Report, in (b) (4) (b) (4). These data cannot be interpreted without a listing of the total mass.
11. Your SE Report includes the addition of constituents that are listed in the Hazardous Substances Data Bank with known toxicities. But, your SE Report does not address all such constituents/substances and why these do not raise new issues of public health. These include, but may not be limited to, (b) (4) (b) (4). Also, it is not clear why the increase of (b) (4) does not cause the new product to raise different questions of public health.
12. The scientific literature shows that (b) (4) influences the way individuals perceive products, including tobacco products. Research shows that (b) (4) influences consumer perceptions of harm, flavor and taste of cigarettes, which in turn may influence the likelihood of product use and initiation of cigarette smoking. However, your SE Report (b) (4) (b) (4).
13. Your SE Report does not include sufficient information needed in order for us to make a determination as to whether or not the tobacco product you have referenced as a predicate is predicate-eligible (grandfathered). The evidence you provided did not indicate specific dates in which commercial marketing of these products occurred in the United States. The information you provided for these submissions consists of a presentation on (b) (4). However, this information does not establish that the products were commercially marketed in the United States as of February 15, 2007.

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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**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:

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

Sincerely,  
(b) (6)

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



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Dear (b) (4)

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- Applicant:** (b) (4)
- Tobacco Product Name<sup>1</sup>:** (b) (4)
- Tobacco Product Category:** Cigarette
- Tobacco Product Sub-Category:** Filtered Conventional Cigarette
- Package Size:** 20 cigarettes
- 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 provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, the information provided does not include sufficient detail to fully identify the composition of the predicate and new tobacco products.
2. Your SE Report does not identify any other type of tobacco other than (b) (4)  
This level of detail does not fully identify the tobacco used in the new and predicate tobacco products. Furthermore, your SE Report states that both the new and predicate tobacco products contain (b) (4) tobacco at an (b) (4) (b) (4). This amount of tobacco needs confirmation because it is

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substantially less than what is contained within other brands of cigarette (700 - 900 mg/cigarette).

3. Your SE Report lists many ingredients as present in (b) (4) quantities. This appears to be incorrect because the reported values for some ingredient quantities are (b) (4) (b) (4)
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6. Your SE Report includes design parameters for the predicate and new tobacco products. However, your SE Report does not provide sufficient detail on product design to fully identify the predicate and new tobacco products. Your SE Report did not provide an adequate description of the predicate and new tobacco products including, but not limited to, lacking the following:
  - a. Graphical representation of the cigarette (including the direction of fade on the tipping to indicate the color on the mouth end);
  - b. Cigarette Weight (mg);
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In addition, verify that the tobacco weight is (b) (4). 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 design parameter listed above.

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from (b) (4) of your SE Report is (b) (4) and the paper ingredients in (b) (4) of your SE Report appear to be for a (b) (4)

8. Your SE Report provides a detailed listing of ingredients in (b) (4) that include levels used for the predicate and new tobacco products. The values provided (b) (4) (b) (4) Accurate product specifications are required to perform relevant evaluation of the data.

9. Your SE Report, in (b) (4) (b) (4) (b) (4) These data cannot be interpreted without a listing of the total mass.

10. Your SE Report includes the addition of constituents that are listed in the Hazardous Substances Data Bank with known toxicities. But, your SE Report does not address all such constituents/substances and why these do not raise new issues of public health. These include, but may not be limited to, (b) (4) (b) (4) Also, it is not clear why the increase of (b) (4) does not cause the new product to raise different questions of public health.

11. The scientific literature shows that (b) (4) influences the way individuals perceive products, including tobacco products. Research shows that (b) (4) influences consumer perceptions of harm, flavor and taste of cigarettes, which in turn may influence the likelihood of product use and initiation of cigarette smoking. However, your SE Report (b) (4) (b) (4) (b) (4)

12. Your SE Report does not include sufficient information needed in order for us to make a determination as to whether or not the tobacco product you have referenced as a predicate is predicate-eligible (grandfathered). The evidence you provided did not indicate specific dates in which commercial marketing of these products occurred in the United States. The information you provided for these submissions consists of a (b) (4) (b) (4) (b) (4) However, this information does not establish that the products were commercially marketed in the United States as of February 15, 2007.

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](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

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)  
(b) (4)

Sincerely,  
(b) (6)

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