November 29, 2017

R.J. Reynolds Tobacco Company
Attention: James Figlar, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000193

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

| Tobacco Product Manufacturer: | R.J. Reynolds Tobacco Company |
| Tobacco Product Name: | True Blue 100 |
| Tobacco Product Category: | Cigarettes |
| Tobacco Product Sub-Category: | Combusted, Filtered |
| Package Type: | Box |
| Package Quantity: | 20 cigarettes |
| Length: | 99 mm |
| Diameter: | 7.9 mm |
| Ventilation: | 54% |
| Characterizing Flavor: | None |
| Modification: | Deletion of a tobacco additive (Casing Flavor (glycerin and water in the casing) and increase in quantity of tobacco additives |

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1 Brand/sub-brand or other commercial name used in commercial distribution
2 The name of the tobacco product being modified is True Box 100s
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX Request, the following must be met:

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at [http://www.fda.gov/TobaccoProducts](http://www.fda.gov/TobaccoProducts). You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov).

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway ([http://www.fda.gov/ESG](http://www.fda.gov/ESG)) using eSubmitter or by mail to:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Submissions delivered by couriers or physical mail will be considered timely if received by the CTP Document Control Center during delivery hours on or before the due date (see [http://www.fda.gov/tobaccoproducts/aboutctp/ucm212531.htm](http://www.fda.gov/tobaccoproducts/aboutctp/ucm212531.htm)); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. The FDA Electronic
Submission Gateway is available for CTP Document Control Center submission receipt seven days a week. We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.11.29 12:41:00 -05'00'

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
November 29, 2017

R.J. Reynolds Tobacco Company
Attention: James Figlar, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000194

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

| Tobacco Product Manufacturer: | R.J. Reynolds Tobacco Company |
| Tobacco Product Name: | 1 True Menthol Green 100 Soft Pack |
| Tobacco Product Category: | Cigarettes |
| Tobacco Product Sub-Category: | Combusted, Filtered |
| Package Type: | Soft Pack |
| Package Quantity: | 20 cigarettes |
| Length: | 99 mm |
| Diameter: | 7.9 mm |
| Ventilation: | 54% |
| Characterizing Flavor: | Menthol |
| Modification: | Deletion of a tobacco additive (Casing Flavor and increase in quantity of tobacco additives (glycerin and water in the casing)) |

1 Brand/sub-brand or other commercial name used in commercial distribution
2 The name of the tobacco product being modified is True Menthol 100s
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

**To market the new tobacco product that is the subject of this EX Request, the following must be met:**

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and  
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at [http://www.fda.gov/TobaccoProducts](http://www.fda.gov/TobaccoProducts). You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov).

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Document Control Center  
Building 71, Room G335  
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Silver Spring, MD 20993-0002

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Submission Gateway is available for CTP Document Control Center submission receipt seven days a week. We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.11.29 12:44:51 -05'00'

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
November 29, 2017

R.J. Reynolds Tobacco Company
Attention: James Figlar, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000195

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

| Tobacco Product Manufacturer: | R.J. Reynolds Tobacco Company |
| Tobacco Product Name: | True Blue Soft Pack |
| Tobacco Product Category: | Cigarettes |
| Tobacco Product Sub-Category: | Combusted, Filtered |
| Package Type: | Soft Pack |
| Package Quantity: | 20 cigarettes |
| Length: | 84 mm |
| Diameter: | 7.9 mm |
| Ventilation: | 61% |
| Characterizing Flavor: | None |
| Modification: | Deletion of a tobacco additive (Casing Flavor) and increase in quantity of tobacco additives (glycerin and water in the casing) |

1 Brand/sub-brand or other commercial name used in commercial distribution
2 The name of the tobacco product being modified is True Kings
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX Request, the following must be met:

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Submission Gateway is available for CTP Document Control Center submission receipt seven days a week. We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.11.29 12:45:54 -05'00'

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
November 29, 2017

R.J. Reynolds Tobacco Company
Attention: James Figlar, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000198

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

<table>
<thead>
<tr>
<th>Tobacco Product Manufacturer:</th>
<th>R.J. Reynolds Tobacco Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco Product Name: 1,2</td>
<td>True Blue 100 Soft Pack</td>
</tr>
<tr>
<td>Tobacco Product Category:</td>
<td>Cigarettes</td>
</tr>
<tr>
<td>Tobacco Product Sub-Category:</td>
<td>Combusted, Filtered</td>
</tr>
<tr>
<td>Package Type:</td>
<td>Soft Pack</td>
</tr>
<tr>
<td>Package Quantity:</td>
<td>20 cigarettes</td>
</tr>
<tr>
<td>Length:</td>
<td>99 mm</td>
</tr>
<tr>
<td>Diameter:</td>
<td>7.9 mm</td>
</tr>
<tr>
<td>Ventilation:</td>
<td>54%</td>
</tr>
<tr>
<td>Characterizing Flavor:</td>
<td>None</td>
</tr>
<tr>
<td>Modification:</td>
<td>Deletion of a tobacco additive (Casing Flavor) and increase in quantity of tobacco additives (glycerin and water in the casing)</td>
</tr>
</tbody>
</table>

1 Brand/sub-brand or other commercial name used in commercial distribution
2 The name of the tobacco product being modified is True 100s
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX Request, the following must be met:

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/egs) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions delivered by couriers or physical mail will be considered timely if received by the CTP Document Control Center during delivery hours on or before the due date (see http://www.fda.gov/tobacco/products/aboutctp/ucm212531.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. The FDA Electronic
Submission Gateway is available for CTP Document Control Center submission receipt seven days a week. We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.11.29 12:47:49 -05'00'

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
November 29, 2017

R.J. Reynolds Tobacco Company  
Attention: James Figlar, Ph.D.  
Senior Vice President, Scientific & Regulatory Affairs  
RAI Services Company  
401 North Main Street  
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000196

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

<table>
<thead>
<tr>
<th>Tobacco Product Manufacturer:</th>
<th>R.J. Reynolds Tobacco Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco Product Name: 1,2</td>
<td>True Blue</td>
</tr>
<tr>
<td>Tobacco Product Category:</td>
<td>Cigarettes</td>
</tr>
<tr>
<td>Tobacco Product Sub-Category:</td>
<td>Combusted, Filtered</td>
</tr>
<tr>
<td>Package Type:</td>
<td>Box</td>
</tr>
<tr>
<td>Package Quantity:</td>
<td>20 cigarettes</td>
</tr>
<tr>
<td>Length:</td>
<td>80 mm</td>
</tr>
<tr>
<td>Diameter:</td>
<td>7.9 mm</td>
</tr>
<tr>
<td>Ventilation:</td>
<td>61%</td>
</tr>
<tr>
<td>Characterizing Flavor:</td>
<td>None</td>
</tr>
<tr>
<td>Modification:</td>
<td>Deletion of a tobacco additive (Casing Flavor) and increase in quantity of tobacco additives (glycerin and water in the casing)</td>
</tr>
</tbody>
</table>

1 Brand/sub-brand or other commercial name used in commercial distribution  
2 The name of the tobacco product being modified is True Box
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX Request, the following must be met:

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions delivered by couriers or physical mail will be considered timely if received by the CTP Document Control Center during delivery hours on or before the due date (see http://www.fda.gov/tobaccoproducts/aboutctp/ucm212531.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. The FDA Electronic
Submission Gateway is available for CTP Document Control Center submission receipt seven days a week. We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman
Date: 2017.11.29 12:46:54 -05'00'

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
November 29, 2017

R.J. Reynolds Tobacco Company
Attention: James Figlar, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000199

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

<table>
<thead>
<tr>
<th>Tobacco Product Manufacturer:</th>
<th>R.J. Reynolds Tobacco Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco Product Name:</td>
<td>True Menthol Green Soft Pack</td>
</tr>
<tr>
<td>Tobacco Product Category:</td>
<td>Cigarettes</td>
</tr>
<tr>
<td>Tobacco Product Sub-Category:</td>
<td>Combusted, Filtered</td>
</tr>
<tr>
<td>Package Type:</td>
<td>Soft Pack</td>
</tr>
<tr>
<td>Package Quantity:</td>
<td>20 cigarettes</td>
</tr>
<tr>
<td>Length:</td>
<td>84 mm</td>
</tr>
<tr>
<td>Diameter:</td>
<td>7.9 mm</td>
</tr>
<tr>
<td>Ventilation:</td>
<td>61%</td>
</tr>
<tr>
<td>Characterizing Flavor:</td>
<td>Menthol</td>
</tr>
<tr>
<td>Modification:</td>
<td>Deletion of a tobacco additive (Casing Flavor) and increase in quantity of tobacco additives (glycerin and water in the casing)</td>
</tr>
</tbody>
</table>

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1 Brand/sub-brand or other commercial name used in commercial distribution
2 The name of the tobacco product being modified is True Menthol Kings
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX Request, the following must be met:

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at [http://www.fda.gov/TobaccoProducts](http://www.fda.gov/TobaccoProducts). You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov).

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Document Control Center  
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Silver Spring, MD 20993-0002

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If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.11.29 12:48:45 -05'00'

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
November 29, 2017

R.J. Reynolds Tobacco Company
Attention: James Figlar, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0000200

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX Request), submitted under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

- **Tobacco Product Manufacturer:** R.J. Reynolds Tobacco Company
- **Tobacco Product Name:** Kent III Silver 100 Soft Pack
- **Tobacco Product Category:** Cigarettes
- **Tobacco Product Sub-Category:** Combusted, Filtered
- **Package Type:** Soft Pack
- **Package Quantity:** 20 cigarettes
- **Length:** 99 mm
- **Diameter:** 7.9 mm
- **Ventilation:** 55%
- **Characterizing Flavor:** None
- **Modification:** Deletion of a tobacco additive (Casing Flavor - cerin and water in the casing) and increase in quantity of tobacco additives (glycerin and water in the casing)

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

2 The name of the tobacco product being modified is Kent III Ultra Lights 100s
Based on our review of your EX Request, we find the new tobacco product specified above exempt from the requirements relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX Request, the following must be met:

1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
2. Ninety days have passed since FDA receipt of your Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at [http://www.fda.gov/TobaccoProducts](http://www.fda.gov/TobaccoProducts). You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway ([http://www.fda.gov/esg](http://www.fda.gov/esg)) using eSubmitter or by mail to:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Submissions delivered by couriers or physical mail will be considered timely if received by the CTP Document Control Center during delivery hours on or before the due date (see [http://www.fda.gov/tobaccoproducts/aboutctp/ucm212531.htm](http://www.fda.gov/tobaccoproducts/aboutctp/ucm212531.htm)); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. The FDA Electronic
Submission Gateway is available for CTP Document Control Center submission receipt seven days a week. We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager at (240) 402 – 5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.11.29 12:49:59 -05'00'

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