DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017 **EXEMPT**

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:[1,2]	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 (b) (4) 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 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. 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 -S
Date: 2017.11.29 12:41:00 -05'00'

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017 **EXEMPT**

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:[1,2]	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 (b) (4) 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. 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.

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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017 **EXEMPT**

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:[1,2]	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 (b) (4) 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.

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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017 **EXEMPT**

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:

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name:[1,2]	True Blue 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:	None
Modification:	Deletion of a tobacco additive (Casing Flavor (b) (4) 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 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/esg) using eSubmitter or by mail to:

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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 12:47:49 -05'00'

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017 **EXEMPT**

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:

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name:[1,2]	True Blue
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Box
Package Quantity:	20 cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	61%
Characterizing Flavor:	None
Modification:	Deletion of a tobacco additive (Casing Flavor (b) (4) 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 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.

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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 12:46:54 -05'00'

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017 **EXEMPT**

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:

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name:[1,2]	True Menthol Green 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:	Menthol
Modification:	Deletion of a tobacco additive (Casing Flavor (b) (4) 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 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.

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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 12:48:45 -05'00'

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 29, 2017

EXEMPT

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:[1,2]	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 (b) (4) 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 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. 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.

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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 12:49:59 -05'00'

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