DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000155

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Gold
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	29%
Characterizing Flavor:	None
Modification:	Removal of tobacco additives: deletion of monograph ink on the barrel of the cigarette (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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

[2] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date see (http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-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: 2017.09.01 08:20:38 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000156

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Royal
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	24%
Characterizing Flavor:	None
Modification:	Removal of tobacco additives: deletion of monograph ink on the barrel of the cigarette (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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Building 71, Room G335
10903 New Hampshire Avenue
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: 2017.09.01 08:21:40 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000157

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Pall Mall Menthol 100's Box
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	98 mm
Diameter:	7.79 mm
Ventilation:	44%
Characterizing Flavor:	Menthol
Modification:	Substitution and removal of tobacco additives: deletion of a tobacco additive (white tipping paper) and addition of a tobacco additive (cork-on-white tipping paper)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Pall Mall Light Menthol 100s Box

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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Building 71, Room G335
10903 New Hampshire Avenue
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: 2017.09.01 08:22:29 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000158

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Pall Mall Menthol Box
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	34%
Characterizing Flavor:	Menthol
Modification:	Substitution and removal of tobacco additives: deletion of a tobacco additive (white tipping paper) and addition of a tobacco additive (cork-on-white tipping paper)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Pall Mall Light Menthol King Box

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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Building 71, Room G335
10903 New Hampshire Avenue
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: 2017.09.01 08:23:21 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000159

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Silver
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	32%
Characterizing Flavor:	None
Modification:	Removal of tobacco additives: deletion of tobacco additive (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

Food and Drug Administration
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Building 71, Room G335
10903 New Hampshire Avenue
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: 2017.09.01 08:24:01 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000160

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Camel Classic Menthol Silver
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	38%
Characterizing Flavor:	Menthol
Modification:	Substitution and removal of tobacco additives: deletion of a tobacco additive (cork-printed tipping paper) and addition of a tobacco additive (white tipping paper)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Camel Lights Menthol Hard Pack

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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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: 2017.09.01 08:24:36 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000161

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Gold 100s
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	98 mm
Diameter:	7.79 mm
Ventilation:	38%
Characterizing Flavor:	None
Modification:	Removal of tobacco additives: deletion of a tobacco additive (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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

[2] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date see (http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-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: 2017.09.01 08:25:16 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000162

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Jade
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	0%
Characterizing Flavor:	Menthol
Modification:	Removal of tobacco additives: deletion of tobacco additive (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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Building 71, Room G335
10903 New Hampshire Avenue
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: 2017.09.01 08:25:55 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000163

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Jade 100s
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	98 mm
Diameter:	7.79 mm
Ventilation:	15%
Characterizing Flavor:	Menthol
Modification:	Removal of tobacco additives: deletion of tobacco additive (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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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Building 71, Room G335
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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: 2017.09.01 08:26:30 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000164

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Jade Silver
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	38%
Characterizing Flavor:	Menthol
Modification:	Removal of tobacco additives: deletion of tobacco additive (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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Building 71, Room G335
10903 New Hampshire Avenue
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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: 2017.09.01 08:27:10 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000165

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Camel Jade Silver 100s
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	98 mm
Diameter:	7.79 mm
Ventilation:	40%
Characterizing Flavor:	Menthol
Modification:	Removal of tobacco additives: deletion of tobacco additive (monogram ink on the barrel of the cigarette)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

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

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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

[2] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date see (http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-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: 2017.09.01 08:27:56 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000167

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Monarch Red 100's Soft Pack
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Length:	99 mm
Diameter:	7.89 mm
Ventilation:	0%
Characterizing Flavor:	None
Modification:	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Monarch Full Flavor 100s Soft Pack

To market the new tobacco product that is the subject of this EX REQ, 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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Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

[3] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

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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: 2017.09.01 08:28:45 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000168

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Monarch Gold 100's Soft Pack
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Length:	99 mm
Diameter:	7.89 mm
Ventilation:	34%
Characterizing Flavor:	None
Modification:	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Monarch Light 100s Soft Pack

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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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: 2017.09.01 08:29:22 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000170

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Monarch Blue 100's Soft Pack
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Length:	99 mm
Diameter:	7.89 mm
Ventilation:	54%
Characterizing Flavor:	None
Modification:	Substitution of tobacco additive: deletion of (b) (4) [redacted] and replacement with (b) (4) [redacted]

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Monarch Ultra Light 100s Soft Pack

To market the new tobacco product that is the subject of this EX REQ, 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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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

[3] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date see (http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-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: 2017.09.01 08:30:01 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000171

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Monarch Red Box
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	0%
Characterizing Flavor:	None
Modification:	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Monarch Full Flavor Box

To market the new tobacco product that is the subject of this EX REQ, 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: 2017.09.01 08:30:44 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000172

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	Monarch Gold Box
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	15%
Characterizing Flavor:	None
Modification:	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Monarch Light Box

To market the new tobacco product that is the subject of this EX REQ, 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.

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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: 2017.09.01 08:31:21 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 01, 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): EX0000173

Dear Dr. Figlar:

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

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1,2]:	GPC Non-Filter Soft Pack
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Non-Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Length:	83 mm
Diameter:	7.89 mm
Characterizing Flavor:	None
Modification:	Substitution of tobacco additive: deletion of (b) (4) and replacement with (b) (4)

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is GPC Non-Filter King Soft Pack

To market the new tobacco product that is the subject of this EX REQ, 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.

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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: 2017.09.01 08:32:01 -04'00'

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