RAI Services Company

**James Figlar, Ph.D.**
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Scientific & Regulatory Affairs
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# 1 COVER LETTERS

## 1.1 Camel Snus Frost (First Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Frost Product TP0000554**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Frost (SKU 134458301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Frost [TP0000554], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Frost, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can significantly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Frost to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus

Frost product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Frost as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Frost:

> "Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Frost | TP0000554 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Frost:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (American Snuff Company) ("ASC") | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000098 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
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| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |

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| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
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| September 6, 2013 | 905(j) Response to PHI AI request | SE0000122 |
| November 13, 2013 | Request for Exemption from Substantial Equivalence (Exemption Request) under section 905(j)(3) | EX0000085 |
| December 18, 2013 | 905(i) Product Registration (ASC) – bulk pouches | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) – bulk pouches | TR0000794<br>TR0000791 |

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| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| August 27, 2014 | 905(j) Response to Scientific Review Notification | SE0000122 |
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| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
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| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| June 23, 2016 | Request for Extension to Respond to Certain FDA Advice/Information Requests for SE0000122 | ** |
| July 12, 2016 | FDA Granting of Extension Request to Respond to Certain FDA Advice/Information Requests for SE0000122 | SE0000122 |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product

is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Frost. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Frost is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Frost product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Frost is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus product described in this Application.

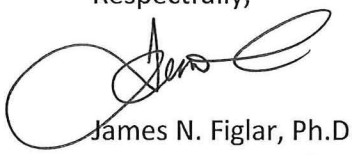
**Trade Secrets or Confidential Commercial Information:**

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publicly available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



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## 1.2 Camel Snus Frost (Second Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Frost Product TP0000554**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Frost (SKU 134458301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Frost [TP0000554], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Frost, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Frost to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Frost product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Frost as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Frost:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

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401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
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Winston-Salem, NC 27101

***Authorized Contacts:***

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Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
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***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
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R.J. Reynolds Tobacco Company

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**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Frost product described in this Application.

**Trade Secrets or Confidential Commercial Information:**

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

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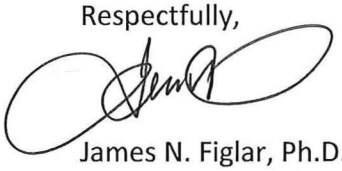
Respectfully,



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## 1.3 Camel Snus Frost (Third Proposed Advertising Execution)

March 31, 2017

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
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**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Frost Product TP0000554**

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In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

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*- On behalf of –*

R.J. Reynolds Tobacco Company
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***Authorized Contacts:***

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Secondary: Michael F. Borgerding, Ph.D.
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Phone: 336-741-6607
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Email: murphyp@rjrt.com

**Brand name and, if applicable, subbrand name of proposed MRTPs:**

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Frost | TP0000554 | 600 | Tin |

**Name of Manufacturer:**

R.J. Reynolds Tobacco Company

**Previous Regulatory Submissions for Camel Snus Frost:**

| Date | Submission | FDA Assigned Number |
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| June 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000098 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000122 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000122 |
| December 20, 2012 | 905(i) Product Registration (ASC) – bulk pouches | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) – bulk pouches | TR0000607<br>TR0000605 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) – bulk pouches | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) – bulk pouches | TR0000698<br>TR0000693 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000122 |
| November 13, 2013 | Request for Exemption from Substantial Equivalence (Exemption Request) under section 905(j)(3) | EX0000085 |
| December 18, 2013 | 905(i) Product Registration (ASC) – bulk pouches | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) – bulk pouches | TR0000794<br>TR0000791 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| August 27, 2014 | 905(j) Response to Scientific Review Notification | SE0000122 |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| June 23, 2016 | Request for Extension to Respond to Certain FDA Advice/Information Requests for SE0000122 | ** |
| July 12, 2016 | FDA Granting of Extension Request to Respond to Certain FDA Advice/Information Requests for SE0000122 | SE0000122 |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

***Satisfaction of Premarket Review Requirements under Section 910 of the Act:***

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product

is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Frost. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Frost is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Frost product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Frost is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Frost product described in this Application.

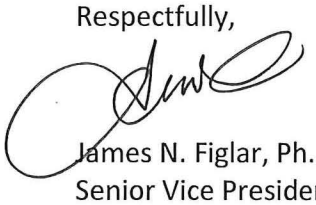
**Trade Secrets or Confidential Commercial Information:**

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
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figlarj@RJRT.com

## 1.4 Camel Snus Frost Large (First Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Frost Large Product TP0007508**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Frost Large (SKU 134530301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Frost Large [TP0007508], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Frost Large, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can significantly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Frost Large to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco

products. Accordingly, the Camel Snus Frost Large product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Frost Large as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Frost Large:

> "Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
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Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
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Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

**Brand name and, if applicable, sub-brand name of proposed MRTPs:**

| Brand Name | Sub-brand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Frost Large | TP0007508 | 1000 | Tin |

**Name of Manufacturer:**

R.J. Reynolds Tobacco Company

**Previous Regulatory Submissions for Camel Snus Frost Large:**

| Date | Submission | FDA Assigned Number |
|---|---|---|
| October 12, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000123 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000123 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000123 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000123 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Frost Large. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Frost Large is substantially equivalent, within

the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Frost Large product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Frost Large is currently on the market in the United States.

***Dates of Prior Meetings with FDA:***

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Frost Large product described in this Application.

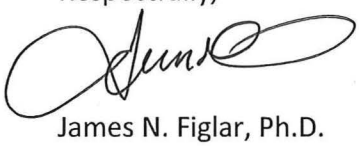
**Trade Secrets or Confidential Commercial Information:**

This Application is and contains non-public, trade secret, and confidential information that is protected under state and federal law from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
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Scientific & Regulatory Affairs
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figlarj@RJRT.com

## 1.5 Camel Snus Frost Large (Second Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Frost Large Product TP0007508**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Frost Large (SKU 134530301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Frost Large [TP0007508], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Frost Large, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Frost Large to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly,

the Camel Snus Frost Large product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Frost Large as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Frost Large:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
Email: borgerm@rjrt.com

Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

**Brand name and, if applicable, sub-brand name of proposed MRTPs:**

| Brand Name | Sub-brand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Frost Large | TP0007508 | 1000 | Tin |

**Name of Manufacturer:**

R.J. Reynolds Tobacco Company

**Previous Regulatory Submissions for Camel Snus Frost Large:**

| Date | Submission | FDA Assigned Number |
|---|---|---|
| October 12, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000123 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
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| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
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| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |

| Date | Submission | FDA Assigned Number |
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| September 6, 2013 | 905(j) Response to PHI AI request | SE0000123 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| March 11, 2015 | 905(j) Response to Scientific Review Notification | SE0000123 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

***Satisfaction of Premarket Review Requirements under Section 910 of the Act:***

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

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***Dates of Prior Meetings with FDA:***

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Frost Large product described in this Application.

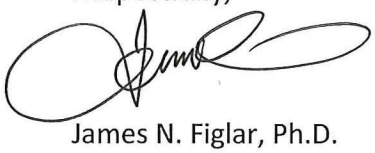
**Trade Secrets or Confidential Commercial Information:**

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
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**James Figlar, Ph.D.**
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figlarj@RJRT.com

## 1.6 Camel Snus Frost Large (Third Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Frost Large Product TP0007508**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Frost Large (SKU 134530301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Frost Large [TP0007508], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Frost Large, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer and respiratory disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Frost Large to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Frost Large

product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Frost Large as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Frost Large:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

**Brand name and, if applicable, sub-brand name of proposed MRTPs:**

| Brand Name | Sub-brand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Frost Large | TP0007508 | 1000 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Frost Large:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| October 12, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000123 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000123 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000123 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| March 11, 2015 | 905(j) Response to Scientific Review Notification | SE0000123 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

***Satisfaction of Premarket Review Requirements under Section 910 of the Act:***

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Frost Large. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Frost Large is substantially equivalent, within

the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Frost Large product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Frost Large is currently on the market in the United States.

***Dates of Prior Meetings with FDA:***

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Frost Large product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,

James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.7 Camel Snus Mellow (First Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Mellow Product TP0000555**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Mellow (SKU 134497301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Mellow [TP0000555], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Mellow, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can significantly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Mellow to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Accordingly, the Camel Snus Mellow product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Mellow as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Mellow:

> "Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
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401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, sub-brand name of proposed MRTPs:***

| Brand Name | Sub-brand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Mellow | TP0000555 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Mellow:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (ASC) | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| July 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000098 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000124 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
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| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000124 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
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| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
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| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
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| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

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Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Mellow product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Mellow is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Mellow product described in this Application.

**Trade Secrets or Confidential Commercial Information:**

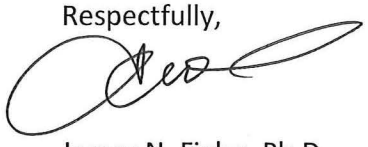
This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.8 Camel Snus Mellow (Second Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Mellow Product TP0000555**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Mellow (SKU 134497301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Mellow [TP0000555], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Mellow, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Mellow to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Mellow product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Mellow as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Mellow:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

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Phone: 336-741-6607
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**Brand name and, if applicable, sub-brand name of proposed MRTPs:**

| Brand Name | Sub-brand Name | Product Identification | Size (mg) | Packaging |
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| Camel Snus | Mellow | TP0000555 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Mellow:***

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| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
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| Date | Submission | FDA Assigned Number |
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| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
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Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Mellow product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Mellow is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Mellow product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

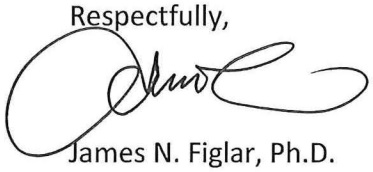
This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.9 Camel Snus Mellow (Third Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Mellow Product TP0000555**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Mellow (SKU 134497301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Mellow [TP0000555], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Mellow, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer and respiratory disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Mellow to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Mellow product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Mellow as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Mellow:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
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Fax: 336-728-0424
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Mellow | TP0000555 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Mellow:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (ASC) | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| July 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000098 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000124 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000124 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000124 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000123 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Mellow. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Mellow is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Mellow product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Mellow is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Mellow product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

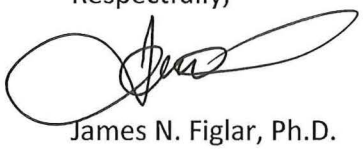
This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
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figlarj@RJRT.com

## 1.10 Camel Snus Mint (First Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Mint Product TP0007509**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Mint (SKU 134532301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Mint [TP0007509], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Mint, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can significantly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Mint to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Mint product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Mint as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Mint:

> "Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
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Email: borgerm@rjrt.com

Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Mint | TP0007509 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Mint:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| October 12, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000125 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000125 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000125 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000125 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Mint. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Mint is substantially equivalent, within the

meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Mint product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Mint is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Mint product described in this Application.

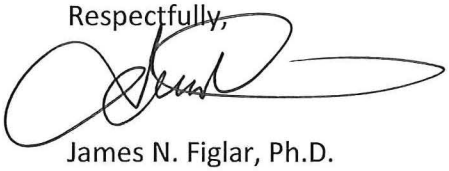
***Trade Secrets or Confidential Commercial Information:***

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.11 Camel Snus Mint (Second Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Mint Product TP0007509**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Mint (SKU 134532301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Mint [TP0007509], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Mint, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Mint to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Mint product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Mint as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Mint:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
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Winston-Salem, NC 27101
Phone: 336-741-7818
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Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
Email: borgerm@rjrt.com

Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

**Brand name and, if applicable, subbrand name of proposed MRTPs:**

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Mint | TP0007509 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Mint:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| October 12, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000125 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000125 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000125 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000125 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Mint. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Mint is substantially equivalent, within the

meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Mint product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Mint is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Mint product described in this Application.

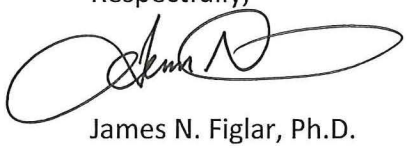
***Trade Secrets or Confidential Commercial Information:***

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.12 Camel Snus Mint (Third Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Mint Product TP0007509**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Mint (SKU 134532301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Mint [TP0007509], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Mint, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer and respiratory disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Mint to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Mint product in this Application qualifies as "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Mint product as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Mint:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
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401 N. Main Street
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Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Mint | TP0007509 | 600 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Mint:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| October 12, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000125 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000125 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000125 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793<br>TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000125 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Mint. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Mint is substantially equivalent, within the

meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Mint product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Mint is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Mint product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,

James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.13 Camel Snus Robust (First Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Robust Product TP0000557**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Robust (SKU 134524301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Robust [TP0000557], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Robust, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can significantly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Robust to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Accordingly, the Camel Snus Robust product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Robust as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Robust:

> "Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
Email: borgerm@rjrt.com

Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

**Brand name and, if applicable, subbrand name of proposed MRTPs:**

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Robust | TP0000557 | 1000 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Robust:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (ASC) | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| June 18, 2010 | 904(a)(1) Change Report 2009-10 | TI0000131<br>TI0000315 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000126 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000126 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000126 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000126 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Robust. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Robust is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Robust product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Robust is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Robust Product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,

James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.14 Camel Snus Robust (Second Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Robust Product TP0000557**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Robust (SKU 134524301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Robust [TP0000557], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Robust, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statis tical modeling of population-level health, an FDA order permitting Camel Snus Robust to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Robust product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Robust as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Robust:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
Email: borgerm@rjrt.com

Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

**Brand name and, if applicable, subbrand name of proposed MRTPs:**

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Robust | TP0000557 | 1000 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Robust:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (ASC) | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| June 18, 2010 | 904(a)(1) Change Report 2009-10 | TI0000131<br>TI0000315 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000126 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000126 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000126 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000126 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

**Satisfaction of Premarket Review Requirements under Section 910 of the Act:**

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Robust. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Robust is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Robust product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Robust is currently on the market in the United States.

**Dates of Prior Meetings with FDA:**

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

**Type of Order Sought:**

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Robust product described in this Application.

**Trade Secrets or Confidential Commercial Information:**

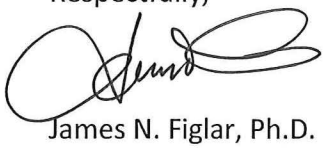
This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
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336-741-7818
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figlarj@RJRT.com

## 1.15 Camel Snus Robust (Third Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Robust Product TP0000557**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Robust (SKU 134524301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Robust [TP0000557], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Robust, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer and respiratory disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Robust to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly, the Camel Snus Robust product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Robust as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Robust:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer and respiratory disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

*- On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Robust | TP0000557 | 1000 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Robust:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (ASC) | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000296 |
| June 18, 2010 | 904(a)(1) Change Report 2009-10 | TI0000131<br>TI0000315 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000126 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |

| Date | Submission | FDA Assigned Number |
|---|---|---|
| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000126 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000126 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
| October 6, 2014 | 904(a)(1) Baseline Reset Ingredient Report | TI0000846 |
| December 17, 2014 | 905(i) Product Registration (ASC) | ** |
| December 17, 2014 | 905(i) Product Registration (RJRT) | ** |
| April 24, 2015 | 905(j) Response to Scientific Review Notification | SE0000126 |
| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 24, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (ASC) | ** |
| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

***Satisfaction of Premarket Review Requirements under Section 910 of the Act:***

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Robust. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Robust is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Robust product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Robust is currently on the market in the United States.

***Dates of Prior Meetings with FDA:***

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Robust product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

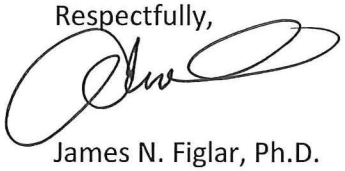
This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.16 Camel Snus Winterchill (First Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Winterchill Product TP0000556**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Winterchill (SKU 134511301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Winterchill [TP0000556], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Winterchill, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can significantly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Winterchill to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco

products. Accordingly, the Camel Snus Winterchill product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Winterchill as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Winterchill:

> "Smokers who switch completely from cigarettes to Camel Snus can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of –*

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-4933
Fax: 336-728-0424
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Winterchill | TP0000556 | 1000 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Winterchill:***

| Date | Submission | FDA Assigned Number |
|---|---|---|
| February 22, 2010 | 905(i) Product Registration (ASC) | TR000023 |
| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
| June 18, 2010 | 904(a)(1) Baseline Ingredient Report | TI0000098 |
| June 18, 2010 | 904(a)(1) Change Report 2009-10 | TI0000131<br>TI0000315 |
| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
| December 16, 2010 | 905(i) Product Registration (ASC) | TR0000210<br>TR0000205 |
| December 16, 2010 | 905(i) Product Registration (RJRT) | TR0000209<br>TR0000207 |
| March 15, 2011 | 905(j) Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce | SE0000127 |
| June 20, 2011 | 905(i) Product Registration (ASC) | TR0000357<br>TR0000359 |
| June 20, 2011 | 905(i) Product Registration (RJRT) | TR0000362<br>TR0000361 |
| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
| June 22, 2012 | 905(i) Product Registration (ASC) | TR0000535<br>TR0000524 |

| Date | Submission | FDA Assigned Number |
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| June 22, 2012 | 905(i) Product Registration (RJRT) | TR0000534<br>TR0000526 |
| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
| November 1, 2012 | 905(j) Response to Administrative AI request | SE0000127 |
| December 20, 2012 | 905(i) Product Registration (ASC) | TR0000604 |
| December 20, 2012 | 905(i) Product Registration (RJRT) | TR0000607<br>TR0000605 |
| June 30, 2013 | 905(i) Product Registration (ASC) | TR0000694<br>TR0000691 |
| June 30, 2013 | 905(i) Product Registration (RJRT) | TR0000698<br>TR0000693 |
| September 6, 2013 | 905(j) Response to PHI AI request | SE0000127 |
| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
| December 18, 2013 | 905(i) Product Registration (RJRT) | TR0000794<br>TR0000791 |
| June 25, 2014 | 905(i) Product Registration (ASC) | ** |
| June 25, 2014 | 905(i) Product Registration (RJRT) | ** |
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| June 24, 2015 | 905(i) Product Registration (RJRT) | ** |
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| December 17, 2015 | 905(i) Product Registration (RJRT) | ** |
| June 22, 2016 | 905(i) Product Registration (ASC) | ** |
| June 22, 2016 | 905(i) Product Registration (RJRT) | ** |
| December 23, 2016 | 905(i) Product Registration (ASC) | ** |
| December 23, 2016 | 905(i) Product Registration (RJRT) | ** |

**FDA-assigned submission tracking numbers have not been provided in response to these submissions

***Satisfaction of Premarket Review Requirements under Section 910 of the Act:***

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Winterchill. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Winterchill is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE Report was submitted prior to March 23, 2011, the Camel Snus Winterchill product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Winterchill is currently on the market in the United States.

***Dates of Prior Meetings with FDA:***

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Winterchill product described in this Application.

***Trade Secrets or Confidential Commercial Information:***

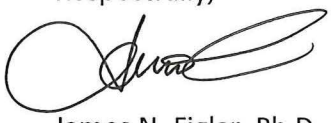
This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only,

RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company

**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
Fax: 336-728-9062
figlarj@RJRT.com

## 1.17 Camel Snus Winterchill (Second Proposed Advertising Execution)

March 31, 2017

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

**Re: Modified Risk Tobacco Product Application for RJRT Camel Snus Winterchill Product TP0000556**

Dear Madam or Sir:

R.J. Reynolds Tobacco Company ("RJRT" or the "Company") submits this Application (the "Application") to the U.S. Food and Drug Administration ("FDA") seeking a modified risk tobacco product ("MRTP") order under Section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "TCA"), for its Camel Snus Winterchill (SKU 134511301) product currently marketed in the United States. With this cover letter, RJRT is submitting a complete MRTP Application, organized according to the recommendations in FDA's Draft Guidance for Modified Risk Tobacco Product Applications, and containing all the information requested therein.

RJRT's testing of Camel Snus products, including Camel Snus Winterchill [TP0000556], has encompassed a wide range of scientific studies using well-known and established methodologies for comparative assessment of tobacco products and associated health risks. RJRT believes that the results of its studies on Camel Snus Winterchill, when combined with the body of U.S. smokeless tobacco epidemiology studies, human clinical studies, preclinical toxicology studies, and chemistry studies of smokeless tobacco and health, provide a sound scientific basis to conclude that, for individuals who are current cigarette smokers, switching completely from smoking cigarettes to Camel Snus can greatly reduce those individuals' risk for lung cancer, oral cancer, respiratory disease, and coronary heart disease. In addition, based on statistical modeling of population-level health, an FDA order permitting Camel Snus Winterchill to be advertised as an MRTP will benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Accordingly,

the Camel Snus Winterchill product in this Application qualifies as a "modified risk tobacco product" as defined by Section 911 of the Act.

RJRT requests that FDA issue an order designating Camel Snus Winterchill as an MRTP and issuing an order permitting the proposed advertising and labeling included in this Application. In this Application, we are proposing the following advertising execution with respect to Camel Snus Winterchill:

> "Smokers who SWITCH COMPLETELY from cigarettes to Camel Snus can greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

In accordance with the Act and FDA's Draft Guidance for Industry: Modified Risk Tobacco Product Applications, RJRT hereby provides the following information to support this Application:

***Company Name and Address:***

RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101

- *On behalf of* –

R.J. Reynolds Tobacco Company
401 N. Main Street
Winston-Salem, NC 27101

***Authorized Contacts:***

Primary: James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-7818
Fax: 336-728-9062
Email: figlarj@rjrt.com

Secondary: Michael F. Borgerding, Ph.D.
Sr. Director – Scientific & Regulatory Affairs
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Patrick A. Murphy, RAC (US)
Director – Scientific & Regulatory Affairs
RAI Services Company
401 N. Main Street
Winston-Salem, NC 27101
Phone: 336-741-6607
Fax: 336-728-4118
Email: murphyp@rjrt.com

***Brand name and, if applicable, subbrand name of proposed MRTPs:***

| Brand Name | Subbrand Name | Product Identification | Size (mg) | Packaging |
|---|---|---|---|---|
| Camel Snus | Winterchill | TP0000556 | 1000 | Tin |

***Name of Manufacturer:***

R.J. Reynolds Tobacco Company

***Previous Regulatory Submissions for Camel Snus Winterchill:***

| Date | Submission | FDA Assigned Number |
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| February 22, 2010 | 905(i) Product Registration (RJRT) | TR0000094 |
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| June 28, 2010 | 905(i) Product Registration (ASC) | TR0000130 |
| June 28, 2010 | 905(i) Product Registration (RJRT) | TR0000129<br>TR0000126 |
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| December 19, 2011 | 905(i) Product Registration (ASC) | TR0000423<br>TR0000426 |
| December 19, 2011 | 905(i) Product Registration (RJRT) | TR0000430<br>TR0000427 |
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| Date | Submission | FDA Assigned Number |
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| September 19, 2012 | 904(a)(3) HPHC Baseline | HC0000067 |
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| December 18, 2013 | 905(i) Product Registration (ASC) | TR0000793 |
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**FDA-assigned submission tracking numbers have not been provided in response to these submissions

***Satisfaction of Premarket Review Requirements under Section 910 of the Act:***

As a general rule, a tobacco product manufacturer must obtain an order from FDA under Section 910(c)(1)(A)(i) of the Act before the manufacturer may introduce a new tobacco product into interstate commerce. Such an order is not required, however, if a manufacturer submits a report under Section 905(j) and FDA issues an order finding that the tobacco product is substantially equivalent to a predicate product and is in compliance with the requirements of the Act.

On March 15, 2011, RJRT submitted a substantial equivalence report ("SE Report") to FDA for Camel Snus Winterchill. The SE Report, along with its associated amendment, set forth the basis for R.J. Reynolds' determination that Camel Snus Winterchill is substantially equivalent, within the meaning of Section 910 of the Act, to a tobacco product commercially marketed in the United States as of February 15, 2007.

Because the SE report was submitted prior to March 23, 2011, the Camel Snus Winterchill product may continue to be legally marketed, pursuant to Section 910(a)(2)(B) of the Act, unless and until FDA issues an order that the tobacco product is not substantially equivalent to its predicate tobacco product. No such order has been issued to date, and Camel Snus Winterchill is currently on the market in the United States.

***Dates of Prior Meetings with FDA:***

| Submission Type | Meeting Date | Topic | Type |
|---|---|---|---|
| 905(j) | 04/05/2013<br>04/09/2013 | Advice/Information requests for provisional products | Telephone |
| 911(g)(1) | 05/29/2014 | MRTPA data requirements | Face-to-face |
| 911(g)(1) | 05/29/2014 | Non-clinical study protocols | Face-to-face |
| 911(g)(1) | 12/5/2015 | MRTPA submission outline | Telephone |

***Type of Order Sought:***

RJRT seeks a risk modification order under Section 911(g)(1) for the Camel Snus Product described in this Application.

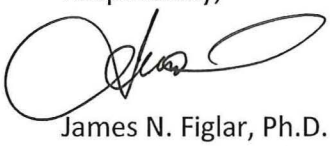
***Trade Secrets or Confidential Commercial Information:***

This Application contains confidential commercial and non-public trade secret information belonging to RJRT or RJRT's vendors, and is exempt from public disclosure.

RJRT understands that Section 911(e) of the Act requires FDA to make this Application publically available, except matters in the Application which are trade secrets or otherwise confidential, commercial information. In order to facilitate FDA's publication of the disclosable portions only, RJRT herein submits both a complete, unredacted version of the Application and a second version with transparent highlights of the information that RJRT has identified as exempt from public disclosure under Section 301(j) and Section 906(c) of the Act. RJRT respectfully requests that FDA maintain confidentiality of the information highlighted in this Application.

RJRT appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure an order under Section 911(g) for the proposed MRTP discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,



James N. Figlar, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs
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RAI Services Company
**James Figlar, Ph.D.**
Senior Vice President
Scientific & Regulatory Affairs
336-741-7818
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figlarj@RJRT.com

## 1.18 Camel Snus Winterchill (Third Proposed Advertising Execution)

March 31, 2017

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

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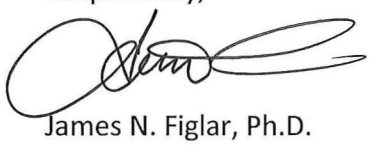

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