U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

MODIFIED RISK GRANTED ORDER– RISK MODIFICATION

U.S. Smokeless Tobacco Company LLC
Attention: Rebecca A. Rivas, Senior Director, Regulatory Submissions
Altria Client Services LLC
601 East Jackson Street
Richmond, VA 23219

FDA Submission Tracking Number (STN): MR0000108

Dear Rebecca A. Rivas:

We completed review of your MRTPA[1] and are issuing a modified risk granted order for the tobacco product identified in Appendix A. This order authorizing the marketing of this modified risk product does not mean FDA "approved" the modified risk product specified in Appendix A; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, misleads, or would mislead consumers into believing, among other things, that the modified risk tobacco product specified in Appendix A is "approved" by FDA (see Section 301(tt) of the FD&C Act). The risk modification order is subject to withdrawal as described in section 911(j) of the FD&C Act.

Based on our review of your MRTPA, we determined that the proposed modified risk tobacco product, Copenhagen Classic Snuff, as described in your application and specified in Appendix A, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. Therefore, we authorize the marketing of the modified risk tobacco product with the following modified risk claim:

> **"IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."**

Under the provisions of section 911 of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the modified risk tobacco product specified in Appendix A, in accordance with this risk modification order. This risk modification order includes requirements related to conditions for marketing under section 911(h) of the FD&C Act and postmarket surveillance and studies (PMSS) under section 911(i) as well as requests related to other record retention and reporting, as outlined in all attached appendices.

[1] Modified Risk Tobacco Product Application (MRTPA) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

This order expires five years from the issue date of this letter. If you wish to renew your order, we recommend that a request for renewal be received by FDA 360 days prior to the expiration date. Your renewal may cross-reference your MRTPA that is subject to this order.

The requirements in this risk modification order are intended to help ensure that your modified risk tobacco product, as actually used by consumers, will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. However, compliance with these requirements alone is not a guarantee that the modified risk tobacco product, as actually used by consumers, will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, particularly if, despite these measures, there is a significant increase in use of your modified risk tobacco product by youth or non-users of tobacco products. FDA will continue to monitor the marketing of your modified risk tobacco product and its impact on the population.

Based on our review of your MRTPA, the marketing requirements in Appendix D are necessary to our conclusion that permitting the marketing of the modified risk tobacco product will benefit the population as a whole. Absent these requirements, a modified risk granted order for this application could not issue consistent with the requirements of section 911 of the FD&C Act. Relatedly, we support certain aspects of your marketing plan, as described in your MRTPA, that are intended to help address the potential for youth use of your products. Specifically, you stated you intend to use the following measures to help reduce youth appeal of your marketing materials, restrict youth access to your products, and limit youth exposure to your labeling, advertising, marketing, and promotion:

- Limit direct mail and email to only adult tobacco consumers who have agreed to receive communications through the Altria Client Services Tobacco Consumer Database.
- Limit consumer engagement programs and marketing interactions at retail locations to only adults who confirm they are current tobacco consumers.
- Implement a retailer trade program aimed at preventing underage sales by training store personnel who sell tobacco products (using We Card® or equivalent training); displaying We Card® or equivalent signage; requiring age verification; displaying retail signage that conveys to adults not to purchase tobacco products for underage use; and adhering to the Smokeless Tobacco Master Settlement Agreement.
- Limit signage at retail locations and require signs in stores be placed within 48” of tobacco products.

We encourage you to implement these measures because they are likely to help further mitigate risks to youth. We also recommend that you take additional steps to limit youth exposure to product marketing at points-of-sale (e.g., requiring advertising to be placed only inside the store) and in print media (e.g., limiting advertising to print publications where 85% or more of the publication’s readership is 21 years of age or older and/or selecting publications that do not over-index for youth).

We remind you that all regulated tobacco products, including the tobacco product specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations, and it is your responsibility to ensure the tobacco product specified in Appendix A complies with all applicable statutory and regulatory requirements. These requirements include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, packaging, labeling, and advertising requirements, and

payment of user fees. FDA will monitor your compliance with all applicable statutes and regulations.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[2,3] using eSubmitter.[4] Alternatively, submissions may be mailed to:

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

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date;[5] if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

[2] https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[3] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[4] https://www.fda.gov/industry/fda-esubmitter
[5] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions, please contact Annie Seaman, MS, Regulatory Health Project Manager, at (301) 796-6103 or Annie.Seaman@fda.hhs.gov.

If you have any questions regarding postmarket activities for the tobacco product subject of this order, please contact Chad Burger, Director, Division of Enforcement and Manufacturing, at CTP OCE-Postmarket@fda.hhs.gov.

Sincerely,

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Todd L. Cecil, Ph.D.
Acting Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – Tobacco Product Subject of This Letter
Appendix B – Amendments Received for This Application
Appendix C – Required Postmarket Surveillance and Studies (PMSS)
Appendix D – Advertising and Promotion Requirements
Appendix E – Recordkeeping and Retention

Appendix A[6,7,8]

[68]

Tobacco Product Subject of This Letter

	[68]
Attributes of MRTPA	
Applicant	U.S. Smokeless Tobacco Company LLC
Product manufacturer	U.S. Smokeless Tobacco Company LLC
Product category	Smokeless Tobacco
Product subcategory	Loose Moist Snuff
Order type	911(g)(1) Risk Modification Order
Modified Risk Claim:	"IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."
Attributes	**Tobacco Product**
STN	**MR0000108**
Product name	Copenhagen Classic Snuff
Submission date	March 19, 2018
Receipt date	March 20, 2018
Package type	Fiberboard Can/Metal Lid
Package quantity	34.02 grams
Characterizing flavor	Tobacco
Nicotine source	Tobacco
Additional Properties	Tobacco cut size: (b) (4) Cuts Per Inch (CPI)

[6] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. https://www.congress.gov/bill/117th-congress/house-bill/2471

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

[8] The characterizing flavor previously identified as "None" has been updated in FDA records to "Tobacco" to accurately reflect that the product provides a tobacco characterizing flavor from the filler. As such, this product does not have any change in characterizing flavor.

Appendix B

Amendments Received for This Application

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
April 10, 2018	April 10, 2018	All	Yes	Correction to Appendix 7.3.2 15 Claim Comprehension and Intentions (CCI) Study SSAP Syntax Code.
July 11, 2018	July 11, 2018	All	Yes	Tabulated master bibliography index.
July 18, 2018	July 18, 2018	All	Yes	Applicant submitted updated version of Table 7.1-17, summary of individual lot results.
August 8, 2018	August 8, 2018	All	Yes	Response to FDA's July 10, 2018, Advice/Information Request letter.
August 27, 2018	August 27, 2018	All	Yes	Response to FDA's August 23, 2018, Clarification Request
February 1, 2019	February 1, 2019	All	Yes	Response to FDA's January 24, 2019, Clarification Request
April 8, 2021	April 8, 2021	All	Yes	Notification for when a complete response to FDA's Deficiency letter will be submitted
September 29, 2021	September 29, 2021	All	Yes	Response to the Deficiency letter issued on March 26, 2021
March 9, 2022	March 9, 2022	All	Yes	Response to FDA's March 7, 2022, request for information regarding labeling and manufacturing information.

Appendix C

Required Postmarket Surveillance and Studies (PMSS)

Under Section 911(i)(1) of the FD&C Act, FDA must require postmarket surveillance and studies for any product for which an applicant received an order under 911(g)(1) in order to: "…determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product."

I. PMSS Content

MRTP Use Behavior and Consumer Understanding and Perception

After receiving authorization, the determination of whether the tobacco product that is the subject of this order (hereinafter, the MRTP), as actually used by consumers, continues to benefit the health of the population as a whole is likely to be driven by use behavior. Therefore, monitoring use of the MRTP in terms of uptake, dual use, and complete switching is required. In particular, your PMSS must assess the extent to which new users of the MRTP were non-users of tobacco products, smokers, or other tobacco product users before initiating the MRTP, and the extent to which such new users of the MRTP become exclusive users or dual users with cigarettes or other tobacco products, including other smokeless tobacco (ST) products, over time. Relatedly, such surveillance must include an ongoing assessment of consumers' understanding of the claim and perceptions of the MRTP. In particular, PMSS must assess the extent to which users of the MRTP understand that, to reduce their risk of lung cancer as described in the modified risk claim, they must switch from smoking cigarettes to using the MRTP exclusively. To adequately assess these impacts, you must conduct PMSS that include assessing users' behavior and consumer understanding at multiple time points.

In addition, FDA has determined that assessing the impact of your MRTP order on uptake of the product requires surveillance of MRTP sales and distribution, which provide information to assess tobacco consumption at the population level. Your PMSS protocols must describe procedures for monitoring and reporting MRTP sales and distribution in the U.S. by major metropolitan areas and channels where the MRTP is sold (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops). Your annual PMSS report must include:

- U.S. sales and distribution of the MRTP by quarter since the granting of your modified risk granted order (for the initial reporting period) or the previous reporting period (for all reports that follow), including, total U.S. sales and distribution reported in dollars and units, and broken down by major metropolitan areas and channels where the product was distributed and sold during the reporting period (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops).
- A brief synthesis and summary of the sales and distribution data for the initial reporting period or the previous reporting period (for all reports that follow), including annual and quarterly growth rate (percent change) in total U.S. sales and distribution of the MRTP since this Order was issued.
- All Universal Product Codes (UPCs) used for the MRTP when selling or distributing it in the U.S.

MRTP Use and Health Risk – Adverse Experiences

In order for FDA to determine whether the MRTP, as actually used by consumers, continues to benefit the health of the population as a whole, your PMSS must include ongoing surveillance of all adverse experiences associated with the use of the MRTP. These experiences may become known to you through any source, including a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. Your PMSS protocols must include procedures for monitoring and analyzing adverse experiences and your annual PMSS report must include:

- A summary of reported adverse experiences for the tobacco product, which includes a listing of all adverse experiences during the reporting period and a cumulative list, including all serious and unexpected adverse experiences previously reported. The summary must be accompanied by an analysis of the reports and a statement of any changes to risk information related to the product including nature, frequency, and potential aggravating factors.

For purposes of this reporting under this order, *serious adverse experience* means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening condition or illness;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of this reporting under this order, *unexpected adverse experience* means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the MRTPA (including the results of human subject investigations) and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the person(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

Surveillance of New Research Study Findings on the MRTP and Consumer Perception, Behavior, or Health

In order for FDA to determine whether the MRTP, as actually used by consumers, continues to benefit the health of the population as a whole, your PMSS must include surveillance of new research study information about the MRTP and consumer perception, behavior, or health. In particular, your PMSS protocol must include procedures for monitoring and assessing findings both in your own studies (i.e., studies conducted by you or on your behalf) and in publications including any new scientific data

(published or otherwise) regarding the MRTP and consumer perception, behavior, or health. Your annual PMSS report must include:

- A summary of significant findings about the tobacco product from research studies conducted by you or on your behalf, whether or not such studies were specifically required under this order.
- A summary of significant findings in publications not previously reported and full copies of the articles. This must include any new scientific data (published or otherwise) on the MRTP and consumer perception, behavior, or health.

Modeling the Impact of the MRTP on Population Health

In order for FDA to determine whether the MRTP continues to benefit the health of the population as a whole, your PMSS must include computational modeling of the impact of the MRTP on population health. Such modeling must incorporate data and information collected through PMSS, including the percentage of former smokers who start using the MRTP; the percentage of current smokers who start using the MRTP and become dual users; the percentage of current smokers who switch completely to the MRTP; the percentage of youth and young adults below the federal minimum age of sale who start using the MRTP; the percentage of individuals who start using the MRTP and then initiate or re-initiate combusted cigarette smoking; the percentage of other tobacco product users, including a specific breakout for other ST products, who start using the MRTP and become dual users; and the percentage of other tobacco product users, including a specific breakout for other ST products, who switch completely to the MRTP. Postmarket modeling must incorporate the latest information on acute and long-term health effects of using the MRTP relative to combusted cigarette smoking in order to assess the short and long-term population health impacts of the marketing. Your annual PMSS report must include:

- A description of the methodological approach used in the model;
- A copy of the model or its underlying code, such that FDA can independently run and verify the model inputs and outputs;
- A description of all model inputs, including the justification for input values and how they were derived from postmarket data and information; and
- A summary of the modeling results and their implications for assessing whether the MRTP continues to benefit the health of the population as a whole.

II. Submitting PMSS Protocols and Reports

Within 30 days of receiving this notice, you must submit complete protocols for your PMSS as required under section 911(i)(2) of the FD&C Act. Label your submission clearly as a "PMSS Protocol," and reference your MRTPA Submission Tracking Number (STN). If you have more than one protocol, each protocol should be a separate submission. If applicable, each protocol should include the name(s) of the principal investigator(s) and materials that demonstrate the relevant professional credentials and training that qualify them to lead the study. Within 60 days of receipt of the protocol(s), FDA will determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol(s) will result in collection of the data or other information that FDA designates as necessary to protect public health, pursuant to section 911(i)(2) of the FD&C Act. FDA will notify you of and provide opportunities to address, any deficiency in the submission. If the PMSS protocol is amended subsequent to FDA approval, FDA must

receive the amended protocol promptly. For protocol amendments that are administrative in nature (e.g., corrections in punctuation or titles), the amended protocol must be received by FDA within 30 days of the update. For protocol amendments that seek to modify the study design (including endpoints, sites, questionnaires, methodology, etc.) or other scientific parameters, you may not initiate the change until you receive FDA approval.

As part of the requirement to conduct PMSS, you must initiate and conduct your PMSS per timeframes established in your protocols and approved by FDA. Note that for PMSS that involve human subjects, the anticipated start date for each study must account for the time required for securing IRB approval, as needed. In addition to specifying the start date, your protocols must contain timelines for completion of major study milestones including, as applicable, the start and completion of participant recruitment, initiation of data collection (per wave, if applicable), completion of data collection, analysis, and report writing. If you deviate from these timelines, we request that you report the deviation within 30 days to FDA.

Section 911(i) of the FD&C Act requires that the results of PMSS be submitted on an **annual basis**. These reports must be identified as “PMSS Report” and reference the MRTPA STN for each report. The PMSS Report must indicate the beginning and ending date of the period covered by the report and must include accomplishments since the last reporting period. For quantitative updates on studies in progress (e.g., participant accrual), reports should describe both interim (since the last reporting period) as well as cumulative (since study initiation) accomplishments. The PMSS Report describing studies in progress must describe the status of PMSS, including, as applicable the status of recruitment, data collection, and analysis; a summary of the study milestones achieved and any deviations from the agreed upon timelines in the protocol; a summary of protocol amendments; and a summary of any preliminary analyses conducted. Once a study is completed, the PMSS Report should include the complete final study report.

Appendix D

Advertising and Promotion Requirements

I. Recordkeeping and Retention

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to establish and maintain the following records:

- Records pertaining to the product's labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
  - Specimens of all labeling (including all labeling variations, such as those reflecting different required warnings), labels, inserts/onserts, instructions, and other accompanying information;
  - Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers;
  - Copies of any formative research studies conducted among any audiences in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the product, and including copies of the stimuli used in testing;
  - Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the product, and including copies of the stimuli used in testing;
  - Copies of any contractual agreements regarding the creation and/or dissemination of the product's labeling, advertising, marketing, and/or promotional materials, including for example, in print media, online or through digital platforms (e.g., social media and mobile applications), such as influencers, bloggers, and ambassadors, on your behalf, or at your direction;
  - Copies of all advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any:
    - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
    - Targeting of specific adult audiences by age-range(s), including young adult audiences, ages 21-24, and other demographic and/or psychographic characteristics that reflect your intended target audience;
    - With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict youth-access and limit youth-exposure to the product's labeling, advertising, marketing, and/or promotion;
    - Use of owned, shared, and/or paid social media to create labeling for, advertise, market and/or promote the products;
    - Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the product;
    - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the product was demonstrated and how access will

be restricted to individuals at or above the federal minimum age of sale of tobacco products; or
    - Use of public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the product;
  - Copies of all records pertaining to media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), and all post-launch delivery-verification reports submitted to you from an accredited source, by channel, by product, and by audience demographics; and
  - Policies and procedures for real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, including documentation of such monitoring activities and implementation of corrective and preventive measures.

II. Annual Reporting

Under section 911(h)(5) of the FD&C Act, this order requires that you submit the following reports to FDA on an annual basis, beginning twelve months from the date of this order. For each twelve-month reporting period, these annual reports must include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000108**. The cover letter should include the STN, static product ID if applicable, and corresponding tobacco product name, applicant name, date of report, and reporting period.
- Records pertaining to the product's labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
  - A summary of all formative research studies conducted among any audiences in the formation of new labeling, advertising, marketing, and/or promotional materials, not previously submitted, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the product, and including the findings of these studies and copies of the stimuli used in testing;
  - A summary of all consumer evaluation research studies conducted among any audiences, not previously submitted, to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the product, and including the findings of these studies and copies of the stimuli used in testing; and
  - A summary of the creation and dissemination of the product's labeling, advertising, marketing, and/or promotional materials including a list of all entities involved and a description of their involvement, including a description of contractual agreements with such entities.
- A description of the implementation of all advertising and marketing plans – whether conducted by you, on your behalf, or at your direction – not previously submitted, including strategic creative briefs and paid media plans, by channel, and the details, dollar amount(s) and flighting of such plans, by channel, including a description of any:
  - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;

  - Targeting of specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect the intended audience(s), including the source(s) of such data;
  - With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the product and limit exposure to the product's labeling, advertising, marketing, and/or promotion;
  - Use of owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the product;
  - Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the product;
  - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the product was demonstrated and how access was restricted to individuals at or above the federal minimum age of sale of tobacco products; or
  - Use of public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the product; including the original date such plans were first used and the date they were discontinued, and a description of all changes to such plans since the last periodic report, by channel;
- An analysis of the actual delivery of advertising impressions, by channel, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), not previously submitted. This analysis must be verified against post-launch delivery-verification reports for paid media submitted to you or entities working on your behalf or at your direction from an accredited source;
- A summary of media tracking and optimization, by channel and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, and including a summary of implementation of any corrective and preventive measures, not previously submitted;
- All final printed labeling (including all variations, such as those reflecting different required warnings) not previously submitted (e.g., if previously submitted under section 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), including the date the labeling was first disseminated and the date when the labeling was discontinued, and a description of all changes to the labeling. The labeling must include all the panels and be presented in the actual size and color with legible text. The labeling must include labels, inserts/onserts, instructions, and any other accompanying information or materials for the product; and
- All final full-color advertising, marketing, and/or promotional materials, published, disseminated to consumers, or for use in engaging or communicating with consumers not previously submitted (e.g., if previously submitted under 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), along with the original date such materials were first disseminated and the date they were discontinued, and a description of all changes to the materials. The materials must be legible, include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text must be provided separately and clearly referenced. Digital media, such as videos and animations must be submitted in a format that FDA is able to open and review.

III. Notifications

Under section 911(h)(5) of the FD&C Act, this order requires that as of the authorization date of your modified risk order, and for a period of six months starting with the initial dissemination of the marketing materials for the MRTP, you submit the following notifications of your marketing plans and materials to FDA and all other labeling, advertising, marketing, and promotion. This notification must be received by FDA at least 30 days prior to dissemination, which includes but is not limited to the publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials.

This 30-day notification requirement to submit the product's labeling, advertising, marketing, and/or promotional materials and plans in advance of their use is not for pre-approval – that is, FDA is not requiring that it review and approve such materials or plans before they may be used. Rather, such advance notification will provide FDA timely access to such materials and plans and, if needed, allow FDA to provide advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation and on the finding that continued marketing of your product will benefit the health of the population as a whole. You may begin disseminating the materials 30 days after the notification is received by FDA.

Each 30-day notification must include:

- A single submission with a cover letter that includes the following subject line: **30-DAY NOTIFICATION for MR0000108**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of notification, and planned dissemination date;
- Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the product, Copenhagen Classic Snuff. The materials must include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the material does not allow for text to be read easily, the text may be provided separately and referenced. Digital media, such as videos, must be submitted in a format that FDA is able to open and review.
- All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the details, dollar amount(s) and flighting of such plans, by channel and by product, including any plans to:
    - Use competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;
    - Target specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect your intended audience(s), including the sources of such data;
    - With respect to individuals below the federal minimum age of sale of tobacco products, actions taken to restrict access to the product and limit exposure to the product's labeling, advertising, marketing, and/or promotion;
    - Use owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the product;

- Use partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the product;
- Conduct consumer engagements – whether by you, on your behalf, or at your direction – including events at which the product will be demonstrated and how access will be restricted to individuals at or above the federal minimum age of sale of tobacco products; and/or
- Use public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the product.

IV. Additional Conditions for Marketing

Under section 911(h)(5) of the FD&C Act, this order requires you to:

- For any of the product's labeling, advertising, marketing, and/or promotion appearing in your **owned digital properties** (e.g., your company-owned, consumer-directed, product-branded website(s) and/or mobile applications)– whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at or above the federal minimum age of sale of tobacco products.
- For any of the product's labeling, advertising, marketing, and/or promotion appearing in any **shared digital properties** (e.g., your product-branded social media accounts, pages and associated content; content promoting your product on your behalf disseminated through another entity's social media accounts) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of the available site-, platform- and content-(e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the product on your behalf through the influencer's account), at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at or above the federal minimum age of sale of tobacco products.
- For any of the product's labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the product running on another company's website; paid advertising for the product running in social media; paid distribution of influencer content; paid advertising in streaming/Over-The-Top video programming; paid advertising in streaming/internet radio content) – whether conducted by you, on your behalf, or at your direction:
  - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of such labeling, advertising, marketing, and/or promotion to only individuals who are at or above the federal minimum age of sale of tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:
    - "First-party" age-verified data is data owned by you (e.g., your customer registration data collected via site traffic to your company-owned website; data you use in direct marketing to your adult smoking customers) that you have age-verified through independent, competent, and reliable data sources; and
    - "Second-party" age-verified data is first-party data owned and age-verified by another competent and reliable entity (e.g., another company's first-party user registration data) to which you have access. Such data must be age-verified by the second party.
    - "First-party" and "second-party" data does not include data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles marketers may use to enhance audience targeting. Such data is not considered age-verified and can only be used in combination with first- and/or second-party age-verified data.

- Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) – whether conducted by you, on your behalf, or at your direction – to **track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products. Such monitoring also requires post-launch delivery verification reports for paid media be submitted to you or entities working on your behalf or at your direction from an accredited source.
- For any use of **partners, influencers, bloggers, and/or brand ambassadors** to create labeling for, advertise, market, and/or promote the product – whether conducted by you, on your behalf, or at your direction – disclose to consumers or viewers, via the use of statements such as "sponsored by [firm name]" in such labeling, advertising, marketing, and/or promotional materials, any relationships between you and entities that create labeling for, advertise, market, and/or promote the product, on your behalf, or at your direction.

The requirements above are intended to help ensure that the MRTP, as actually used by consumers, will continue to benefit the health of the population as a whole. Limiting youth initiation of the product and, relatedly, youth exposure to advertising and marketing materials for the product are important factors in the population health benefit analysis. Accordingly, FDA also recommends limiting youth exposure to any of the tobacco product's labeling, advertising, marketing, and/or promotion appearing in print media publications.

After receiving authorization, the determination of whether the MRTP, as actually used by consumers, continues to benefit the health of the population as a whole is likely to be driven by use behavior. An uptake in youth initiation and use of the product would have a significant negative impact on the population health benefit analysis. To help ensure that your product, as actually used by consumers, continues to benefit the health of the population as a whole, we strongly recommend that you take measures to limit youth initiation and use of the product, beyond limiting advertising and promotion as required in this order. For example, we strongly recommend you adopt the following measures related to all digital sales of your product:

- For any **digital sales** – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, to prevent the sale of the product to individuals who are under the federal minimum age of sale of tobacco products.

Relatedly, we request that you submit the following information to CTP on an annual basis:

- A summary of the implementation and effectiveness of any policies and procedures regarding verification of the age and identity of purchasers of the product.
- A summary of the implementation and effectiveness of any policies and procedures regarding restrictions on youth access to the product.

We remind you that if FDA can no longer make the determination that your product, as actually used by consumers, will benefit the health of the population as a whole, FDA must withdraw the modified risk order, after an opportunity for an informal hearing. See under section 911(j)(1) of the FD&C Act.

Although adopting the measures above is not in itself a guarantee that the product will continue to benefit the health of the population as a whole, it is an important step in helping to ensure that there are no grounds for withdrawal of your order.

Appendix E

Recordkeeping and Retention

The risk modification order for your MRTP is effective for 5 years from the issue date of the order. If you wish to renew your order, we recommend you submit a request for renewal 360 days prior to the end of your effective timeframe. In order to help ensure that your risk modification order meets the standard for renewal and to help expedite the review of any renewal application(s), we request that you establish and maintain the records listed below. The records should be retained for a period of not less than four years from the date of distribution of the last batch of the tobacco product listed in your order under section 911(g)(1) of the FD&C Act. The records should be legible, written in English, and upon request, available for inspection and copying by officers or employees duly designated by the Secretary. Please note that Appendices C and D require you to periodically submit some of these records to FDA (e.g., in PMSS reports and/or advertising and promotion-related reports).

- The MRTPA and amendments submitted prior to the orders
- Postmarket reports, as described in Appendix C, including adverse experience reports and all relevant documentation associated with the experience
- Records of all nonclinical or clinical studies, including:
  - Source data;
  - Study protocols (including statistical analysis plan);
  - Amendments showing the dates and reasons for any protocol revisions;
  - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or non-approvals;
  - Informed consent forms;
  - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
  - Investigator financial disclosure statements;
  - Progress reports;
  - Monitoring reports;
  - Adverse experience reports;
  - Case report forms/subject diaries/medical records/laboratory reports;
  - Subject data line listings/observation records;
  - Test article accountability records;
  - Study results/protocol summaries/study reports; and
  - Certifications and amendments to certifications
- Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) of the product
- Records pertaining to the sale, distribution, or other disposition of the product, specifically:
  - A list of distributors and retailers of the product, including brick-and-mortar and digital. For the purposes of this order, here and throughout the document, “digital” includes internet/online and mobile;
  - Any available information (not to include personally identifiable information) about product purchases, such as purchasers’ demographics (e.g., age, gender, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use); and
  - With respect to individuals under the federal minimum age of sale of tobacco products, policies and procedures regarding restrictions on access to the product, including purchaser age and identity verification processes.

- Health hazard analyses, if performed voluntarily or directed by FDA
- Records pertaining to any and all complaints associated with the product that you receive or of which you are aware.