

4.1 LABELS, LABELING, AND ADVERTISING

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4.1. LABELS, LABELING, AND ADVERTISING

4.1.1. Purpose

Section 911(d)(1) of the FD&C Act requires that any application for a modified risk tobacco product include “any proposed advertising and labeling.”

The U.S. Food and Drug Administration (FDA) also recommends in Section V.A.1. of its Modified Risk Tobacco Product Application (MRTPA) Draft Guidance, that applicants include a “description of how [the applicant] intend[s] to communicate the modified risk claim(s) to consumers . . .”

This section provides the proposed advertising and labeling that will communicate the modified risk claim and describes the marketing communication vehicles for the modified risk claim, upon FDA authorization of this application for the candidate product.

4.1.2. Introduction

U.S. Smokeless Tobacco Company (USSTC) submits this application for the candidate product with the following modified risk claim:

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

The candidate product is a grandfathered product (FDA Grandfather Status # GF1200194) ([Appendix 2.3-1](#)), commercially marketed in the U.S. as of February 15, 2007. As such, it is not a new tobacco product as defined by FDCA Section 910(a) (1) and does not require premarket review and authorization.¹ The candidate product will be marketed as Copenhagen® Snuff Fine Cut.

Communicating accurate information about the health risks of tobacco products can provide a public health benefit. Based on analyses of the Population Assessment of Tobacco and Health (PATH) Study, Wave 1 (United States Department of Health and Human Services et al., 2017), approximately 2.3 million adult smokeless tobacco (ST) users² also smoke cigarettes. Eighty percent of these individuals and 90 percent of all adult smokers perceive ST as having “about the same” or more harm than cigarettes. However, the scientific evidence, as presented in Section 6.0 of this application, supports the conclusion that ST presents reduced risk of lung cancer. Of further significance, based on PATH Study data, half

¹ Copenhagen® Fine Cut and variants thereof have been on the market since 1822. Since 2007, USSTC made minor modifications to Copenhagen® Snuff Fine Cut, which are the subject of a separate pending Substantial Equivalence review. The candidate product subject to the MRTPA is the product for which FDA granted grandfathered status (Grandfather Number – GF1200194) on November 1, 2012.

² Based on ALCS analysis of PATH Wave 1 data Sep 12, 2013 – Dec 14, 2014; “ST users who also smoke cigarettes” (i.e., dual users) include those who meet the following two conditions: (a) having used ST at least 20 times in their lifetime and were using ST every day or some days at the time of assessment and (b) having smoked at least 100 cigarettes in their lifetime and were using ST every day or some days at the time of assessment. Cigarette smokers include those who report having smoked at least 100 cigarettes in their lifetime and were smoking every day or some days at the time of assessment.

of adult consumers of ST and cigarettes, and of cigarettes overall, say they are “somewhat likely” or “very likely” to use a tobacco product if that product “made a claim that it was less harmful to health than other tobacco products.”

We propose the modified risk claim to accurately inform adult tobacco consumers (ATC) about the relative risk of lung cancer associated with use of the candidate product as compared to cigarettes. Allowing ATC to make an informed decision about the relative risks of the candidate product should result in an increase in the adoption of the candidate product by smokers over time. Furthermore, communicating the modified risk message across multiple marketing vehicles would encourage cigarette smokers to switch to the less harmful candidate product, especially among those already receptive to non-combustible products like MST.

4.1.3. Marketing Approach

USSTC is committed to marketing its products responsibly by building relationships between our brands and ATC, while taking steps to limit our reach to unintended audiences. We verify the age of consumers and have them certify that they are smokers and/or ST consumers before they may receive branded one-to-one communications, access one of our brand websites, or enter one of our MST brands’ qualified adult-only facilities. For print advertising (newspapers, magazines, periodicals, or other publications), we choose publications that have predominantly adult readership as marketed by the publisher and validated through reliable survey evidence.

4.1.3.1. Consumer Communications

USSTC uses the following marketing communication vehicles:

- One-to-one communications: We use direct mail and e-mail to communicate about our brands and products, as well as to invite ATC to consumer engagement programs. We maintain a secure database of qualified ATC who have consented to hear from USSTC (the Altria Client Services Adult Tobacco Consumer Database). USSTC will stop sending communications to any person who requests to no longer receive such information.
- Consumer websites: Our age-restricted brand websites enable ATC to interact with our brands and products.
- Consumer marketing activities: We offer consumer engagement programs that support USSTC’s brands and products. These activities may occur at retail stores, qualified adult-only facilities, or adult-only facilities.

4.1.3.2. Determining Print Advertising Placement

We use print advertising to build awareness of our brands with ATC. We only select publications with predominantly adult readership.

When we use print advertising, we limit these ads to newspapers, magazines, and other publications that meet the criteria of an "adult publication" under FDA's definition. Under this standard, an adult publication is one:

- whose readers younger than 18 years of age constitute 15 percent or less of the total readership, as measured by competent and reliable survey evidence; and
- that is read by fewer than two million persons younger than 18 years of age, as measured by competent and reliable survey evidence.

4.1.3.3. Trade Programs

USSTC offers trade programs for retailers and wholesalers to help responsibly manage USSTC products within the ST category. Effective category management principles define our retail trade program, including:

- merchandising our products in an organized way in a non-self-service location;
- having our brands in-stock and available;
- having our most popular brands in the preferred positions;
- clearly communicating price and promotional offers; and
- preventing underage access.

Importantly, the retail program includes several features to prevent underage access to tobacco products including:

- 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.

We also limit the number of USSTC signs at retail locations and require that all USSTC signs inside the store are within 48" of the tobacco category to limit placement of signage.

4.1.4. Proposed Copenhagen[®] Snuff Fine Cut Advertisements and Marketing Materials

4.1.4.1. Overview

Upon FDA authorization of this MRTPA, USSTC will implement a marketing plan for Copenhagen[®] Snuff Fine Cut using some or all of the following marketing communication channels: print publications; direct mail; e-mail; the Copenhagen[®] branded website

(FreshCope.com); promotional cards distributed in person to ATC; bottom can labels; and point-of-sale materials.

4.1.4.2. Print Advertisements

Print advertisements may communicate the proposed modified risk claim to ATC accompanied by the required rotational FDA-mandated warnings ([Appendix 4.1-1](#)).

4.1.4.3. Direct Mail Materials

Direct mail materials may communicate the proposed modified risk claim to ATC. Each direct mail item may be personalized to address the ATC by name. The direct mail materials would only be distributed to ATC on the Altria Client Services Adult Tobacco Consumer Database. In the sample direct mail material depicted in [Appendix 4.1-2](#) and [Appendix 4.1-3](#), the placeholder “Dear Andrew” represents a hypothetical ATC for whom the direct mail material is intended.

4.1.4.4. E-Mail

USSTC may communicate the proposed modified risk claim via email to ATC on the Altria Client Services Adult Tobacco Consumer Database. In the sample e-mail depicted in [Appendix 4.1-4](#), the placeholder “Dear Andrew” represents an ATC e-mail recipient.

4.1.4.5. FreshCope.com Website Pop-up Screen

On FreshCope.com, the branded website for Copenhagen®, a website pop-up screen with the modified risk claim may appear on the Copenhagen® Snuff Fine Cut product “tile,” located within the Copenhagen® Products Page on FreshCope.com ([Appendix 4.1-5](#)).

Only the pop-up box in the screen depicted in [Appendix 4.1-5](#) contains the modified risk claim. [Appendix 4.1-5, Page 2](#) illustrates how the pop-up screen would appear over the Copenhagen® Snuff Fine Cut product “tile” on the FreshCope.com website. Websites, by nature, feature dynamic content that changes on a frequent basis. The pop-up screen will always be located within the Copenhagen® Snuff Fine Cut product “tile.” However, the imagery featured on the Copenhagen® Snuff Fine Cut product “tile” and the text featured on the Copenhagen® Snuff Fine Cut product “tile” is subject to change.

4.1.4.6. Promotional Card

Promotional cards may be distributed in person to ATC as follows:

- by brand ambassadors representing the Copenhagen® brand to ATC who visit USSTC’s Copenhagen® qualified adult-only facilities or during Copenhagen® brand promotions at adult-only facilities; and
- by retail clerks and/or Altria Group Distribution Company representatives during an age-verified tobacco purchase in retail stores (e.g., stores) where tobacco products are sold.

[Appendix 4.1-6](#) depicts a card with the text “Here’s something we thought you might like to know.” located on the exterior fold. The interior fold, as shown in [Appendix 4.1-7](#), will communicate the proposed modified risk claim.

4.1.4.7. Bottom Can Label

USSTC may also use a bottom can label to communicate the proposed modified risk claim to ATC. These labels, which would contain the claim as demonstrated in [Appendix 4.1-8](#), would be applied to the bottom of the can during the manufacturing process.

4.1.4.8. Point of Sale

Point of sale materials with the proposed modified risk claim, as shown in [Appendix 4.1-9](#), may be used in all or some of the following executions within retail stores:

- as a sign placed behind the checkout counter and within 48” of where ST products are sold;
- as an outward facing sign on the entry door of retail stores; or
- as a sign placed within the parking lot of retail stores.

4.1.5. Summary

USSTC submits this application in order to communicate to ATC accurate information about the health risks of using the candidate product. The proposed modified risk claim, conveyed across multiple vehicles over time, will increase the likelihood that adult smokers will choose to transition to the candidate product. If authorized by the FDA, USSTC will responsibly implement its modified risk tobacco product marketing campaign to reach ATC, while taking steps to limit the reach to unintended audiences.

4.1.6. Literature Cited

United States Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse, United States Department of Health, Human Services Food, Drug Administration Center for Tobacco Products, & USDHHS. (2017). *Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files*. Retrieved from: <http://doi.org/10.3886/ICPSR36231.v13>.