

The attached document represents CTP's then-current thinking on certain aspects of tobacco regulatory science. The information contained herein is subject to change based on advances in policy, the regulatory framework, and regulatory science, and, is not binding on FDA or the public. Moreover, this document is not a comprehensive manual for the purposes of preparing or reviewing tobacco product applications. FDA's review of tobacco product applications is based on the specific facts presented in each application, and is documented in a comprehensive body of reviews particular to each application.

Given the above, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents and webinars prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. This document does not bind FDA in its review of any tobacco product application and thus, you should not use this document as a tool, guide, or manual for the preparation of applications or submissions to FDA.

**Memorandum**

**Date:** October 15, 2019

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**Subject:** Social Science Reviewer Guide for SE Reports

# Social Science Reviewer Guide: SE Reports

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## INTRODUCTION

This document provides information that has been used to support **Social Science** reviews of SE reports. Note that this document is not intended to be an exhaustive catalogue of information relevant to review of an SE Report and reviewers are reminded that there may be more recent literature or studies that can be cited in support of your reviews. The information contained herein is subject to change based on advances in policy, the regulatory framework, and regulatory science, and, is not binding on FDA or the public. Moreover, this document is not a comprehensive manual for the purposes of preparing or reviewing tobacco product applications. FDA's review of tobacco product applications is based on the specific facts presented in each application and is documented in a comprehensive body of reviews specific to each application.

Given the above, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents and webinars prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. This document does not bind FDA in its review of any tobacco product application and thus, interested persons should not use this document as a tool, guide, or manual for the preparation of applications or submission to FDA.

A reviewer may use this document as a **general** guide for your review. Use the suggested deficiencies contained in this document to the extent that they are appropriate for the submission(s) you are reviewing. Additionally, you can use the text and/or references below as appropriate. **If you identify topics or references that should be added, please inform your Team Lead and/or Branch Chief.**

## SCIENTIFIC EVALUATION OF THE SE REPORT

The Social Science review focuses on how the differences in characteristics between the new and predicate product may alter appeal and/or reduce barriers to subsequent initiation, increase barriers to cessation, or may influence use patterns including the amount of the product used. Examples of product characteristics that influence initiation, cessation, or use patterns include but are not limited to product flavors, portion or quantity, format, or novelty. Information that can help demonstrate that differences in characteristics do not cause the new tobacco product to raise different questions of public health (DQPH) may include, but is not limited to:

- Quantitative studies that measure appeal and/or behavioral intentions to use the new product compared to the predicate product
- Qualitative studies on appeal, perceptions, attractiveness and/or behavioral intentions of the new product compared to the predicate product
- Data about tobacco use behavior such as, initiation among non-users, increased use or decreased cessation, as well as the amount of use among users of the new product compared to the predicate product,
- Other research and analyses conducted to prepare for the product's introduction into the marketplace.

In the rest of this document, starting from the section directly below, we describe deficiencies that Social Science has commonly identified in SE Reports. A deficiency is identification of an issue where the manufacturer has not provided sufficient information to demonstrate that the difference(s) in characteristics between the new and predicate tobacco products does not raise DQPH. Put differently, deficiencies are drawn from the scientific review and state issues within an SE Report that are required to be addressed by the applicant.

## **COMMON SOCIAL SCIENCE ISSUES**

Common issues identified in Social Science review of SE Reports are grouped by the tobacco product category (cigarettes, roll-your-own (RYO) tobacco, and smokeless tobacco) and include sample language that reviewers have used previously to describe a change in characteristics comparing the new product to the predicate product. FDA notes that these examples are illustrative only and are not intended to convey that any such differences specific to an individual SE Report would or would not result in a determination of SE.

The following are examples of common Social Science issues that raised differences in characteristics between the new and predicate products and a suggested framework for review of these issues.

## CIGARETTES

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### Portion Count

#### Increase or Decrease in Cigarette Count:

*Suggested framework for review:* For SEXXXXXXX, there is an increase or decrease in portion count between the new and predicate products. The new product[s] contain XX cigarettes per pack, whereas the predicate product contains 20 cigarettes per pack, a XX% increase or decrease.

Per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” signed 12/7/17, this change, based on CTP’s experience and the evidence available to CTP at this time, does not cause the new product(s) to raise DQPH and thus does not result in a Social Science deficiency. See memo entitled “Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.”

### Product Dimensions

#### Change in Cigarette Length

*Suggested framework for review:* For SEXXXXXXX the length of the new product is XX mm, whereas the predicate product is XX mm in length, representing an XX% [increase; decrease] in length. It is possible that changes in the physical dimensions of the cigarette design may affect consumer perceptions of the product. Physical dimension may encompass length or diameter of the product (e.g., 83 mm vs. 100 mm or standard versus slim cigarettes). One experimental study recruited 160 adult ever-smokers and found that the physical dimensions (length and diameter) of cigarette sticks influenced consumers’ ratings of cigarette attractiveness, perceived quality, and strength of taste (Borland & Savvas, 2013). Additionally, one focus group study with 50 female non-smokers and 25 female occasional smokers, found that physical dimensions of the cigarette stick (e.g., slim vs. standard) influenced consumer interest, appeal, perceptions of taste, and perceptions of harm (Moodie, Ford, Mackintosh, & Purves, 2014). Another study conducted focus groups with 48 adolescents and found that slimmer diameters and, to a lesser extent, shorter length may decrease perceptions of harms while increasing perceptions of appeal and attractiveness (Ford, Moodie, MacKintosh, & Hasting, 2014). The currently available evidence suggests that changes in the length of the cigarette stick may influence consumer perceptions of the product. However, at this time, there is insufficient scientific evidence on the influence of the length of cigarettes on consumer perceptions to indicate that a XX% change in length would cause the new product to raise DQPH from a Social Science perspective.

#### Change in Cigarette Diameter

*Suggested framework for review:* For SEXXXXXXX, the diameter of the cigarette rod in the new product is XX, whereas the predicate product is XXXX in diameter, representing an XX% [increase; decrease] in diameter. Conventional cigarettes range from 7.5 – 8.0 mm in diameter. Slim cigarettes range from 5 - 6 mm in diameter (US Centers for Disease Control and Prevention, 2010). Superslim cigarettes are even smaller in diameter.

Talhout et al. (2018) summarized scientific literature regarding an individual’s perception of cigarette design features, including stick diameter. Research suggests that individuals perceive slim cigarettes as less harmful, better tasting, and generally, more appealing than conventional cigarettes. Moodie et al. (2015) found that women perceived slim cigarettes as stylish and appealing. Ford et al. (2014) found that adolescents perceived slim and superslim cigarettes as less harmful and weaker tasting than conventional cigarettes. Additionally, Carpenter et al. (2007) and Carpenter et al. (2005) found evidence

from tobacco industry documents that slim cigarettes are perceived as feminine, sexy, and attractive in one's hand.

Though research has shown that consumers have perceived slimmer cigarettes as less harmful, better tasting, and more appealing, the evidence is limited to focus group data from Scotland and industry document data. Based on the available scientific literature, the XX% increase/decrease in product diameter does not cause the new tobacco products to raise DQPH from a Social Science perspective.

### **Novel Product Characteristic**

#### Menthol Bead

*Suggested framework for review:* In SEXXXXXXX the applicant indicates that the new product [insert name of product] contains a crushable menthol capsule while the predicate product [insert name of product] does not.

The addition of the menthol capsule or bead changes the product format. The addition of the menthol capsule is an innovation to a product (i.e., a cigarette) whose basic design features, from the perspective of the consumer, have not changed for decades. The addition of a menthol flavored capsule thus increases the novelty of the new product when compared to both non-mentholated or traditionally mentholated cigarettes predicate products. Novelty-seeking is considered one of the fundamental drivers which underlie consumer behavior (Hirschman, 1980) and novelty-seeking personality traits are among the most important predictors for initiation of tobacco use (U.S. Department of Health and Human Services, 1994). Further, the product can be either mentholated or non-mentholated, as determined by the action of the user. The literature states that choice is inherently rewarding (Leotti & Delgado, 2011; Bown et al. 2003)—that is, individuals derive pleasure from the opportunity to choose. This research suggests that the versatility of a product with a menthol capsule, wherein consumers can choose how to experience the product, confers appeal in that it enhances consumer choice. This property in and of itself is likely appealing to all consumers, even while the specific options (menthol cigarette vs. non-menthol cigarette) may not be. Additionally, the menthol capsule cigarette provides the consumer with the choice to crush a liquid-filled capsule embedded in a cigarette filter that flavors the cigarette smoke, thus altering the consumer's sensory experience of smoking (Karles et al, 2013). In the patent for "Filtered cigarette incorporating a breakable capsule" (R.J. Reynolds, 2003) discussed including a capsule to create a more appealing and attractive cigarette to consumers and states that "...it is desirable to provide a cigarette that is capable of providing different sensory experiences at the discretion of a smoker." This suggests that products containing menthol capsules in the filter, designed for discretionary use by the smoker, deliver menthol in a way that makes the novelty of this product have a special appeal to smokers and provides them a different overall smoking experience different from traditional menthol cigarettes. Therefore, this change in format to include a menthol capsule may increase appeal as it offers flavor versatility and choice through this novel feature.

Several studies support the appeal of flavor capsule products, including menthol capsules, compared to cigarettes without flavor capsules (Thrasher et al. 2016; Emond et al. 2018; Moodie et al. 2017). In a study conducted by Thrasher et al., US smokers who usually smoked cigarettes with crushable capsules perceived their brand as more stylish, smoother, and less harmful compared to people who smoked regular premium brands (Thrasher et al., 2016). Emond et al. (2018) found that among US adults ages 18-44 who were current or former cigarette smokers, daily smokers that used flavor capsule cigarettes starting smoking after 18 years of age compared to daily smokers of non-mentholated and traditionally mentholated cigarettes. Among current every day smokers ages 18-25 in the study, flavor capsule users

more commonly reported pack design as the reason for choosing the product compared to users of menthol cigarettes (Emond et al., 2018).

The available data indicates that capsule cigarettes can impact appeal and perceptions of harm in youth and other vulnerable consumers in the US (Thrasher et al., 2016). Perceptions of reduced harm of cigarettes is associated with an increased risk of initiation among youth (Song et al., 2009; Strong et al. 2019). Therefore, a difference in perception for cigarettes with crushable menthol capsules compared to cigarettes without capsules or without menthol as the characterizing flavor may increase the risk of initiation based on data on appeal and reduced harm perceptions of capsule cigarettes. The data available in the US on the differences in perceptions between a cigarette with and without a crushable capsule, as well as data on the association between reduced harm perceptions of cigarettes and initiation in general indicate that the addition of a crushable capsule may raise DQPH.

The supporting memo “Crushable Menthol Bead” signed on 1/6/17 further describes why this design feature may raise DQPH from a Social Science perspective. See the memo entitled “Crushable Menthol Bead.”

*Example Deficiency:*

Your new product has a crushable menthol capsule which differs from the corresponding predicate product. It is possible that introducing a new tobacco product with a crushable menthol capsule in the filter may change consumer perceptions of the product. For example, the new product that includes a crushable menthol capsule may enhance product appeal. In order to assess the new product, we need information about how the addition of a crushable menthol capsule impacts consumer perceptions and use. Submit any information that demonstrates that the capsule in the new product does not raise DQPH. This information may include, but is not limited to:

- Quantitative studies that measure appeal and/or behavioral intentions to use the new product compared to the predicate product
- Qualitative studies on appeal, perceptions, attractiveness and/or behavioral intentions of the new product compared to the predicate product
- Data about tobacco use behavior such as, dependence, initiation among non-users, increased use or decreased cessation among users of the new product compared to the predicate product
- Other research and analyses conducted to prepare for the product’s introduction into the marketplace.

**Filter**

*Suggested framework for review:* In SEXXXXXX, a functional filter is added in the new tobacco product. The predicate tobacco product does not have a filter, rather it has a hollow tube which serves as mouthpiece.

The addition of a functional filter may affect consumer perception and/or use of the new tobacco product. The functional filter may be visible to consumers and potentially affect consumer perceptions and/or use of the product. For example, if the new filter is referenced in product labeling or marketing, consumers may perceive the new tobacco product as less harmful to health than the predicate tobacco product, which may increase product appeal and influence product initiation.

Talhout et al. (2018) summarized scientific literature regarding and individual’s perception of cigarette design features, including filters. Research suggests that individuals perceive filtered cigarettes to be less



harmful than unfiltered cigarettes. In 1997, Hastrup conducted a study of current smokers (N=53) and former smokers (N=24), finding that a majority of both groups believed filters made cigarettes safer. Cummings and colleagues (2004) conducted a nationally representative survey of 1,046 adult smokers. They found that 71% of respondents incorrectly believed (or responded “don’t know”) that a filter makes a cigarette less dangerous than the same cigarette without a filter. The majority (65%) of respondents also incorrectly believed (or responded “don’t know”) that filters, in general, made cigarettes less dangerous for smokers. Borrelli and colleagues (2007) conducted a study to examine harm perceptions among nurses (N=178), who were both smokers and non-smokers. Among this sample, 44% of all nurses believed that the addition of filters made cigarettes less harmful. Lastly, Talhout and colleagues (2018) also report that a new trend in filter design is to use filters as a way for cigarette manufacturers to distinguish their brands.

Since consumers tend to perceive filtered cigarettes as less harmful, there may be increases in product appeal, potentially leading to initiation or product switching. These behaviors may raise DQPH from a Social Science perspective.

*Example Deficiency:*

Your new tobacco products have a functional filter compared to the predicate product, which has no filter and consists of a hollow tube serving as mouthpiece. It is possible that introducing a functional filter may change consumer perceptions of the new tobacco products. For example, research suggests that consumers perceive filtered cigarettes to be less harmful than unfiltered cigarettes. You did not provide any information about how the change in filter, specifically the addition of a functional filter, impacts consumer perceptions and appeal of the new tobacco products. To assess the new tobacco products, we need information about this. Submit any information that demonstrates that the new tobacco products with a functional filter do not raise DQPH. This information may include, but is not limited to:

- Quantitative consumer perception studies that measure appeal and/or behavioral intentions to use the new tobacco products compared to the predicate tobacco products
- Qualitative consumer perception studies on appeal, perceptions, attractiveness, and/or behavioral intentions of the new tobacco products compared to the predicate tobacco products
- Data about tobacco use behavior such as dependence, initiation among non-users, and/or increased use or decreased cessation among users of the new tobacco products compared to the predicate tobacco products
- Market analyses (e.g., sales and/or market segmentation analyses to identify likely consumers of the products)
- Other research and analyses conducted to prepare for introduction of the new tobacco products into the marketplace

**Flavor**

Change from Non-Characterizing to Menthol

In SEXXXXXXX the applicant indicates that the new product [insert name of product] contains a characterizing menthol flavor while the predicate product [insert name of product] does not.

*Suggested framework for review:* A change from the predicate product, which does not contain menthol, to the new product, which does contain menthol, may raise DQPH with respect to the impact of new menthol products on initiation of tobacco use. The appeal of menthol cigarettes, especially among youth, has been linked to their portrayal in marketing as having a smoother taste and being less

harsh, which may be appealing to newer smokers or those curious about experimentation (Henningfield et al. 2003; Klausner, 2011).

Menthol cigarettes are used more frequently by youth and young adult smokers than adult smokers (Villanti et al. 2017), especially youth and young adults that have smoked for less than a year, suggesting they appeal to youth and may be associated with increased initiation as compared to non-menthol cigarettes. In the first wave (2013-2014) of the Population Assessment of Tobacco and Health (PATH) Study, 43% of ever cigarette smoking youth ages 12 to 17 reported that their first cigarette smoked was a menthol cigarette (Cohn et al. 2019). In the Truth Initiative Young Adult Cohort Study, 52% of new young adult smokers ages 18- 34 used a menthol cigarette at first use (D'Silva et al. 2018). The demographic profiles of menthol smokers and non-menthol smokers differ. Specifically, compared to non-menthol cigarettes, menthol cigarettes are disproportionately smoked by adolescents, Blacks/African Americans, females, (Caraballo & Asman, 2011; Rath et al. 2016).

A survey of current adolescent and adult smokers in 2010 found that among menthol smokers, if they were no longer able to obtain menthol cigarettes, they reported that they would most likely try to quit smoking/smoke less or seek out alternative sources of menthol, such as in a smokeless tobacco product (O'Connor et al. 2012). In that study, over 80% of menthol smokers reported that they would be willing to try a non-menthol cigarette, suggesting that in the absence of a menthol cigarette, current menthol smokers might be willing to switch to a non-menthol cigarette.

The evidence for initiation of menthol cigarettes, especially among youth and young adults, suggests that the new mentholated product is likely to have an impact on initiation rates compared to the non-mentholated predicate product and, therefore, may raise DQPH.

*Example Deficiency:*

Compared to the predicate products, your new products contain the characterizing flavor of menthol. Research suggests that a taste enjoyment of menthol has been associated with initiation and continued used of cigarettes, particularly among youth and young adults. It is possible that introducing the products with menthol may make the products more appealing to consumers than the predicate products. Thus, it is possible that the change to characterizing flavors may raise DQPH. In order to assess the new product, we need information about how the changes in characterizing flavors impact consumer perceptions and product appeal. This information may include, but is not limited to:

- Consumer perception studies comparing attitudes, beliefs and behavioral intentions for the taste of the new product to the predicate product
- Taste panel results comparing the new and predicate products on taste, liking, or intentions to use based on the flavor; or identification by the taste panel of the predominant flavor of the predicate product and differences between the predominant flavors of the predicate and new products
- Market analyses (e.g., sales and/or market segmentation analyses to identify likely consumers of the product) and how they compare to the predicate product
- Other research and analyses conducted to prepare for the products' introduction into the marketplace

Change from Menthol to Non-Characterizing

In SEXXXXXXX, there is the removal of menthol characterizing flavor in the new products.

*Suggested framework for review:* The appeal of menthol cigarettes, especially among youth, has been linked to their portrayal in marketing as having a smoother taste and being less harsh, which may be appealing to newer smokers or those curious about experimentation (Anderson, 2011; Klausner, 2011; Kreslake, Wayne, & Connolly, 2008; Yeger, 2011). However, the differences in flavor between the new and predicate products are changes from a characterizing flavor to a non-characterizing flavor. From a Social Science perspective, this change in the new product does not raise DQPH beyond those of the predicate product.

## **SMOKELESS**

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### **Portion Quantity**

#### Increase/Decrease in Portion Quantity

*Suggested framework for review:* The applicant indicates that there is a difference in the quantity per portion between the predicate product and the new product.

The total quantity per portion changed from [XX units] of tobacco per portion in the predicate product to [XX units] of tobacco per portion in the new product, a [XX% increase/decrease].

Per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” signed 12/7/17, such a change, based on CTP’s experience and the evidence available to CTP at this time, does not cause the new product(s) to raise different question of public health and thus does not result in a Social Science deficiency. See memo entitled “Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.”

### **Portion Count**

#### Increase/Decrease in Portions Per Package

*Suggested framework for review:* The count of [product type] in the new product differs from the count of [product type] in the predicate product. In SEXXXXXXX, the new product, [Name of New Product], has [XX units] compared to the [XX units] in the predicate product, [Name of Predicate Product]. This quantity change represents an increase/decrease of [X.X%].

Per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” signed 12/7/17, such a change, based on CTP’s experience and the evidence available to CTP at this time, does not cause the new product(s) to raise different question of public health and thus does not result in a Social Science deficiency. See memo entitled “Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.”

### **Package Quantity**

#### Increase/Decrease in Package Quantity

*Suggested framework for review:* The applicant indicates that there is a difference in the package quantity between the predicate product and the new product.

The total package quantity changed from [XX units] of tobacco per [container] in the predicate product to [XX units] of tobacco per [container] in the new product, a [XX% increase/decrease].

Per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” signed 12/7/17, such a change, based on CTP’s experience and the evidence available to CTP at this time, does not cause the new product(s) to raise different question of public health and thus does not result in a Social Science deficiency. See memo entitled “Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.”

## Flavor

### Non-Characterizing to Characterizing

*Suggested framework for review:* When compared to the predicate product, the new products [SEXXXXXXX, SEXXXXXXX, and SEXXXXXXX] contain changes in characterizing flavors. For SEXXXXXXX the applicant indicates that the sub-brand flavor for the new product is “XXXXX” while the sub-brand flavor for the predicate product is “XXXXX”.

For SEXXXXXXX there are differences in characterizing flavor between the new and predicate products. When compared to the predicate product, the new products contain characterizing flavors. Research suggests that enjoyment of flavor has been associated with initiation and continued use of smokeless tobacco products, particularly among youth and young adults (Villanti et al. 2017; Kenny et al., 1996; Lisnerski et al., 1991). In a study in which U.S. smokers sampled various tobacco lozenges and snus products, including a product with no characterizing flavor, only 1% of participants chose the product with no characterizing flavor as the most-liked product compared to other products with flavors such as Wintergreen, Frost, Java, Natural, and others (Hatsukami et al., 2011). Additionally, when asked to choose one product to use during a 2-week period of cigarette abstinence, 0 out of 97 participants chose the product with no characterizing flavor (Hatsukami et al., 2011). Hatsukami et al. (2011) concluded that, “The dislike for this product may be due in part to the taste of the product, which was specifically developed for the tobacco users in Sweden” (p. 235). Initial qualitative studies in the domain of snus suggest a potential effect of flavors on appeal (Choi et al. 2012, p. 2091; Wackowski et al., 2011). An analysis of U.S. convenience store sales data indicated that flavors are contributing to the growth in sales of moist snuff (Delnevo et al., 2014), and flavored tobacco products may be particularly appealing to youth (e.g., Minaker et al., 2014). Further, studies examining consumer product choice for smokeless tobacco initiation and continuation have found that the majority of smokeless users first and current choice of smokeless tobacco product was flavored, including mint, compared to non-flavored products (Oliver et al., 2013; Smith et al., 2016). Thus, the changes in characterizing flavor between the new and predicate products may cause the new products to raise DQPH from a Social Science perspective.

### *Example Deficiency:*

Compared to the predicate products, your new products contain characterizing flavors. Research suggests that a taste enjoyment of flavor has been associated with initiation and continued use of smokeless tobacco products, particularly among youth and young adults. It is possible that introducing the products with the new flavors may make the products more appealing to consumers than the predicate products. Thus, it is possible that the change to characterizing flavors may raise DQPH. In order to assess the new product, we need information about how the changes in characterizing flavors impact consumer perceptions and product appeal. This information may include, but is not limited to:

- Consumer perception studies comparing attitudes, beliefs and behavioral intentions for the taste of the new product to the predicate product
- Taste panel results comparing the new and predicate products on taste, liking, or intentions to use based on the flavor; or identification by the taste panel of the predominant flavor of the predicate product and differences between the predominant flavors of the predicate and new products
- Market analyses (e.g., sales and/or market segmentation analyses to identify likely consumers of the product) and how they compare to the predicate product
- Other research and analyses conducted to prepare for the products’ introduction into the marketplace

#### Characterizing to Non-Characterizing

*Suggested framework for review:* For SEXXXXXXX there are differences in characterizing flavors between the new and predicate products. For SEXXXXXXX the applicant indicates that the flavor for the new product is “XXXX” while the flavor for the predicate product is “XXXXX”

Research suggests that enjoyment of flavor has been associated with initiation and continued use of smokeless tobacco products, particularly among youth and young adults (Villanti et al. 2017; Oliver et al., 2013; Kenny, Quigley, & Regennitter, 1996; Lisnerski, McClary, Brown, Martin, & Jones, 1991). However, the evidence for initiation of flavored moist snuff, suggests that the new product in its non-characterizing flavor (i.e., XXXX) is not likely to have a negative impact on initiation rates compared to the predicate (i.e., XXXX) product. Thus, based on currently available scientific evidence, the changes from characterizing flavor in the predicate products to a non-characterizing flavor in the new products do not cause the new products to raise DQPH beyond those of the predicate products from a Social Science perspective.

#### Characterizing to Characterizing

*Suggested framework for review:* In SEXXXXXXX the new product contains a change in characterizing flavor when compared to the predicate product. The flavor of the new product is “XXXX (e.g. mint)” while the flavor of the predicate product is “XXXXX (e.g. wintergreen).”

Research suggests that enjoyment of flavor has been associated with initiation and continued use of smokeless tobacco products, particularly among youth and young adults (Villanti et al. 2017; Oliver et al., 2013; Kenny, Quigley, & Regennitter, 1996; Lisnerski, McClary, Brown, Martin, & Jones, 1991). Since the differences in flavor between the new and predicate products are not changes between non-characterizing and characterizing flavors, as indicated by use of flavor descriptors in the new and predicate products, based on current scientific evidence, these changes in flavor do not cause the new products to raise DQPH beyond those of the predicate product, from a Social Science perspective.

#### Non-Characterizing to Non-Characterizing

*Suggested framework for review:* In SEXXXXXXX the new product contains a change in flavor when compared to the predicate product. The flavor of the new product is “XXXX (e.g. Crisp)” while the flavor of the predicate product is “XXXXX (e.g. Rich).”

Introducing the new product with different flavors may make the products more appealing to consumers than the predicate products. Research suggests that enjoyment of flavor has been associated with initiation and continued use of smokeless tobacco products, particularly among youth and young adults (Villanti et al. 2017; Oliver et al., 2013; Kenny, Quigley, & Regennitter, 1996; Lisnerski, McClary, Brown, Martin, & Jones, 1991). Based on currently available scientific evidence, since the differences in flavor between the new and predicate products are not changes between non-characterizing and characterizing flavors, as indicated by use of flavor descriptors in the new and predicate products, these changes in flavor do not cause the new products to raise DQPH beyond those of the predicate product, from a Social Science perspective.

## **Novel Product Feature**

### Package Format - Loose to Pouched/Portioned

*Suggested framework for review:* In SEXXXXXXX there is a change in product format from a loose predicate product to portioned new products.

The applicant indicated that the predicate products are in a loose design format and the new products are in a portioned/pouched format. Since the new products are portioned by the manufacturer and the predicate products are portioned by the consumer, there is a change in the product design format. This difference in design format may affect perceptions and/or use of the product. It is possible that the portioned product would be easier to use, especially for more inexperienced users, which would lower barriers to initiation and use of the new products. (Connolly, 1995; Tomar et al. 1996). Delnevo et al. (2014) examined Nielsen sales data in the US from 2005 to 2011 and found that the market share of portion pouches increased while other formats remained stable or decreased. In addition, focus group research found that participants described portioned and pouched smokeless products as less messy, more discrete, and potentially more appealing to new users as compared to other products (Choi et.al, 2012; Wray et. al, 2012; Liu et. al, 2014).

Based on this information a change from loose to portioned/pouched smokeless products may raise DQPH from the Social Science perspective.

#### *Example Deficiency:*

Your new product is a [PORTIONED/LOOSE] product, a change from the [LOOSE/PORTIONED] predicate product. It is possible that introducing the product in a different format may change consumer perceptions of the product. For example, there is the possibility that the portioned product would be perceived as easier to use, especially for more inexperienced users. The resulting perception may lower barriers to initiation of the new products.

In order to assess the new product, we need information about how the [LOOSE/PORTIONED] format change impacts consumer perceptions and product appeal. Submit any information that demonstrates that the [LOOSE/PORTIONED] format of the new product does not raise DQPH. This information may include, but is not limited to:

- Consumer perception studies comparing attitudes, beliefs, and behavioral intentions for the new product to the predicate product
- Market analyses (e.g., sales and/or market segmentation analyses to identify likely consumers of the products)
- Studies on purchasing frequency that demonstrate that the amount of product used per day or per week is similar between the predicate and new tobacco products
- Other research and analyses conducted to prepare for the products' introduction into the marketplace



## **ROLL YOUR OWN TOBACCO**

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### **Package Quantity**

#### Change in RYO Filler (Tobacco) Quantity

*Suggested framework for review:* The new product contains an increase/decrease in the quantity of roll-your-own tobacco. The new product, PRODUCT NAME, contains XX units of tobacco, whereas the predicate product, PRODUCT NAME, contains Xx units of tobacco; an XX% increase/decrease.

Per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” signed 12/7/17, such a change, based on CTP’s experience and the evidence available to CTP at this time, does not cause the new product(s) to raise different question of public health and thus does not result in a Social Science deficiency. See memo entitled “Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.”

### **Portion Count**

#### Paper/Filter/Tube Count

*Suggested framework for review:* [In the SE report/In all the SE reports/In SE reports STN SEXXXXXXX] the new product, [New product name if this only applies to one product], has [Insert quantity XX] [insert product such as leaves of paper/tubes/etc...] [specify per what unit] compared to [Insert quantity YY] [insert product such as leaves of paper/tubes/etc...] [specify per what unit] in the predicate product, [Predicate product name], an [increase/decrease] of XX.X%.

Per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” signed 12/7/17, such a change, based on CTP’s experience and the evidence available to CTP at this time, does not cause the new product(s) to raise different question of public health and thus does not result in a Social Science deficiency. See memo entitled “Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products.”

### **Product Dimensions**

#### RYO Tubes/Papers/Filters Dimensions

*Suggested framework for review:* [In the SE report/In all the SE reports/In SE reports STN SEXXXXXXX] the new product [New product name if this only applies to one product], is [larger/smaller] than the predicate product [Predicate product name if this only applies to one product]. The dimensions of the new product [New product name if this only applies to one product] are [Insert dimensions/size with units] whereas the dimensions of the predicate product [Predicate product name if this only applies to one product] are [Insert dimensions/size with units]. This represents a XX.X% [increase/decrease] in product size.

As the [New product name/New products] is/are [larger/smaller] than the predicate product, [Predicate product name] the size of [insert product such as leaves of paper/tubes/etc...] could affect consumer perceptions. However, based on currently available scientific evidence on the influence of the size of [insert product such as leaves of paper/tubes/etc...] on consumer perceptions, use intentions, or product use, such a [increase/reduction] in product size does not cause the new product to raise DQPH from a Social Science perspective and thus does not result in a Social Science deficiency.



## ADDITIONAL COMPONENTS OF THE SOCIAL SCIENCE REVIEW OF SE REPORTS

In this section, we discuss review of the Health Information Summary and the potential option for Social Science reviewers to defer issues identified in the SE reports to other disciplines.

### HEALTH INFORMATION SUMMARY

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#### Brief Overview

Section 910(a)(4)(A) requires that applicants, as part of a section 905(j) substantial equivalence submission, include an adequate summary of any health information related to the tobacco product or state that such information will be made available to any person upon request. There are several possible options manufacturers can use to provide the required health information summary/statement, applicants can:

- A. Provide an accurate, complete, not false or misleading summary to FDA that includes all of the following:
  - i. Description of the new tobacco product;
  - ii. Description of the predicate tobacco product;
  - iii. List of all differences in characteristics between the predicate and new tobacco products;
  - iv. Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise DQPH; and
  - v. Any research or data they have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”
- B. Truthfully state that they will provide the information described in section 910(a)(4) of the FD&C Act, upon request, to any person, and in response to all such requests provide the information listed in item A.i.-v. above.
- C. Truthfully state that they will provide the information described in section 910(a)(4) of the FD&C Act, upon request, to any person, and in response to all such requests provide the following information to requestors:
  - i. A copy of their SE Report redacted only to the extent necessary to exclude research subject identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63 and
  - ii. The information in item A.v. above.

If the manufacturer provides a health information summary, Social Science reviewers examine the information submitted by manufacturers to determine if what they’ve provided would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances. Such information would cause the product to be in violation of section 911 of the FD&C Act, and the product would be adulterated under section 902 of the FD&C Act.

Per the memo “Current policy regarding section 910(a)(4), as part of an SE Report an applicant is required to ‘provide an adequate summary of any health information related to the tobacco product or

state that such information will be made available upon request to any person.” signed 8/4/17, any statement an applicant is *required* to include in a health information summary pursuant to § 910(a)(4) does not constitute a modified risk claim. See the memo entitled “Current policy regarding section 910(a)(4), as part of an SE Report an applicant is required to ‘provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request to any person.’” Under proposed § 1107.18(j)(5), neither the applicant’s health information summary, nor health information provided in response to a request may contain a statement that would amount to an unauthorized modified risk claim upon the introduction or delivery for introduction of the proposed new product into interstate commerce (see section 911 of the FD&C Act). For the purposes of § 1107.18(j)(5), statements made in an SE application (e.g., comparisons of HPHCs between the new and predicate tobacco products) typically would not amount to unauthorized modified risk claims, as an SE application is neither label, labeling, or advertising, nor any action directed to consumers. Section 911(b)(2)(A) of the FD&C Act (21 U.S.C. 387k(b)(2)(A)). Therefore, Social Science’s review of a health information summary for potential § 911 violations should be limited to information that is not required under § 910(a)(4).

*Suggested framework for review:*

The applicant provided a health information summary [indicate in what section, on what page, or using or other information to locate it] [for STNs SEXXXXXXX] that contains potential violations of Section 911. For example, the applicant states “[INSERT ONE OR MORE EXAMPLES OF POTENTIAL 911 VIOLATION(S) HERE]”.

**Example Deficiency:**

In [all of your SE Reports/SEXXXXXXX], you provided a summary of health information in accordance with section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The summary of health information provided contains (a) potential violation(s) of section 911 of the FD&C Act. Section 911 of the FD&C Act prohibits, without an MRTP marketing order, the representation, explicitly or implicitly, that a tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products. Specifically, statements in your health information summary such as, “[INSERT ONE OR MORE EXAMPLES OF POTENTIAL 911 VIOLATION(S) HERE]” may convey to consumers that this product/these products [Select appropriate section of 911: present(s) a lower risk of tobacco related disease than other tobacco products/does not contain or is free of a substance or contains a reduced level of a substance (and/or), or presents a reduced exposure to a substance in tobacco smoke]. Consequently, the submitted health information summary in each SE Report appears to potentially violate section 911 of the FD&C Act. Provide either a revised health information summary or evidence that the use of this language would not violate the requirements of section 911. We refer you to the adequate summary language regarding section 910(a)(4) of the FD&C Act, which lists out potential options to comply, elsewhere in this letter.

## **Deferral to Other Disciplines**

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Deferring an issue occurs when you identify an issue of concern within the SE report that falls outside the purview of Social Science review. List issues that you have identified in your Social Science review but which you are deferring to other disciplines in this section. You should clearly identify the discipline to which you are deferring, the issue, and the page number(s) where the issue can be found in your review. See example below of an issue deferred to other disciplines.

**Example of a Deferred Issue:**

Flavor: In instances in which the applicant changes ingredients that may impart characterizing flavor but does not change the characterizing flavor name, defer to the Chemistry Team.

Defer to Chemistry: In SE [XXXXXXX], the applicant indicates that the new product contains vanilla, whereas the predicate product does not contain any vanilla. The SE report lists the same characterizing flavor for the new and predicate products. The potential chemical issues related to flavor will be addressed by the chemistry reviewer.

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