



American Heart Association.



October 19, 2020

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Role of the Tobacco Products Scientific Advisory Committee in Modified Risk Tobacco Product Proceedings

Dear Director Zeller:

In the Family Smoking Prevention and Tobacco Control Act (TCA) Congress mandated the creation of the Tobacco Products Scientific Advisory Committee (TPSAC or the Committee) and gave it several specified roles, including in the evaluation of Modified Risk Tobacco Product (MRTP) applications. Specifically, it required that MRTP applications be submitted to TPSAC and that TPSAC provide FDA with its recommendations on the applications before FDA issues or denies MRTP orders. For TPSAC to carry out its mandated function, and for the FDA and the public to have the benefit of TPSAC's assessment of the scientific evidence necessary for it to make the recommendations that are required for a decision on each application, TPSAC must be given the opportunity to evaluate the scientific issues and articulate its individual and collective views as to whether an application has met the required scientific standard.

We are writing because the role TPSAC has been playing in modified risk proceedings has not been consistent with the letter or spirit of the TCA. The Committee's role has been increasingly marginalized; it has not been asked, or provided an opportunity, to indicate whether applications meet the required scientific standards, and more recently, it has not been provided with an opportunity to vote on the most important scientific issues necessary for it to make recommendations concerning such a determination.

FDA's marginalization of TPSAC's role has been compounded by FDA's failure to give due deference to TPSAC's conclusions regarding Philip Morris' application for IQOS. On the IQOS application, TPSAC provided clear, consistent, scientifically-based guidance on key population health questions establishing that the product did not meet the scientific threshold required for MRTP authorization.¹ Nevertheless, FDA recently issued exposure modification orders for the IQOS system.

¹ A majority—and at times, overwhelming majority—of TPSAC members did not believe (a) the applicant demonstrated that reductions in exposure were reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality (5 of 8 votes), (b) it was likely that U.S. smokers would switch completely to IQOS (7 votes of low likelihood, 2 for medium, and 0 for high), or (c) that consumers would accurately understand the risks of IQOS as conveyed in the proposed modified risk labeling and advertising (9 of 9 votes). In addition, eight of nine voting members found a medium-high likelihood that U.S. smokers would become long-term dual users of IQOS and conventional cigarettes, and three found a medium-high likelihood that U.S. never

In short, the diminished role FDA has given to TPSAC, combined with the manner in which it appeared to disregard TPSAC's conclusions regarding the IQOS application, is inconsistent with the TCA and the traditionally important role of FDA scientific advisory committees to enhance public trust in FDA decisions regarding industry applications. FDA must reverse course and enable TPSAC to provide objective, credible public scrutiny to MRTP applications and recommendations as to whether such applications meet the required scientific standard.

I. STATUTORY AND REGULATORY BACKGROUND

Section 911(f)(1) of the Food, Drug, and Cosmetic Act (FDCA) requires FDA to refer every MRTP application to TPSAC. In turn, “[n]ot later than 60 days after the date an application is referred” to TPSAC, it “shall report its recommendations on the application” to FDA.² The final decision to issue or deny a modified risk order rests with FDA, but the statute makes receipt and consideration of TPSAC's recommendations an essential component of FDA's review of every MRTP application. In other words, no modified risk application may be acted upon without TPSAC making recommendations on whether to grant or deny an application and on the scientific issues necessary to make such a determination.

The unique importance of TPSAC's role in the MRTP application review and authorization process is illustrated by the contrast between its mandatory MRTP role and the discretionary role of other scientific advisory committees respecting review of new products under other sections of the FDCA. For example, when reviewing a drug or biologic with a novel active ingredient, FDA need not seek advisory committee input as long as it explains its decision for not making a referral in its action letter.³ FDA has similar discretion to seek advisory committee input on premarket approval applications for a novel medical device.⁴ The TCA's MRTP provisions do not afford such discretion to FDA. Rather, Congress left no doubt that TPSAC is a critical part of the process by requiring it to make substantive recommendations on FDA's review and authorization of MRTP applications.

FDA has provided little guidance as to how it views TPSAC's role in light of the statutory language. The process FDA uses to refer individual MRTP applications to the Committee was first discussed at the April 30, 2013 TPSAC meeting.⁵ In the fiscal year (FY) 2013 TPSAC Report, FDA indicated that “[t]he [MRTP

smokers would become established IQOS users. January 25, 2018 TPSAC Meeting Transcript, at 559, 583, 594, 607, available at <https://www.fda.gov/media/111450/download> (last accessed Oct. 2, 2020).

² 21 U.S.C. § 387k(f)(2) (emphasis added).

³ See 21 U.S.C. § 355(s) (requiring referral of only some new drug and biologic license applications to an advisory committee for “review,” unless FDA states its reasons for not referring the application in the action letter on the application).

⁴ 21 U.S.C. § 360e(c)(3) (requiring referral of a device premarket approval application to an advisory committee panel for “study and for submission ... of a report and recommendation respecting approval of the application” only upon request of an applicant, unless FDA determines there would be substantial duplication of information already reviewed by a panel).

⁵ The Campaign for Tobacco-Free Kids submitted comments discussing the rigorous standards for scientific proof required by Section 911 of the TCA, including the historical basis for Congress mandating a demanding scientific review, and outlined the statutory role of TPSAC in FDA's assessment of whether an applicant has met its burden to provide such proof, noting that the TCA requires TPSAC involvement in FDA's evaluation of MRTP applications and TPSAC recommendations on each application. Comments of Campaign for Tobacco-Free Kids (CTFK) in Docket No. FDA-2013-N-0001, April 30, 2013 TPSAC meeting re process for TPSAC consideration of modified risk tobacco product applications (April 23, 2013), available at <https://bit.ly/2GgskKS> (last accessed Oct. 2, 2020). Public health

application] recommendation would likely be a compilation of TPSAC meeting materials (e.g., transcript, slides, etc.) and may include a brief written report.”⁶ The FY 2013 TPSAC Report also stated, “Further scientific, administrative and legal review will be needed for FDA to determine the precise processes to be used for MRPT [sic] application review, referral to the TPSAC, and the TPSAC’s recommendation regarding the application.” To our knowledge, no further clarification of TPSAC’s role has been provided.⁷

The 2008 FDA guidance document on voting procedures for advisory committee meetings (Voting Procedures Guidance) identifies two ways that advisory committees typically communicate advice or recommendations to the Agency:

First, FDA learns from the discussion and exchange that occurs among advisory committee members, and from individual recommendations and suggestions made during the discussion of any advisory committee meeting. Second, advisory committees often vote on a question or series of questions posed to the committee during a committee meeting. As the agency makes its final decision, FDA seriously considers the recommendations made by advisory committees, including the advisory committee deliberations and voting.⁸

The Voting Procedures Guidance, however, is not legally binding and concerns only uniform voting procedures for when votes *are* taken, not when votes *should be* taken.⁹ It was also developed before the enactment of the TCA and thus does not address TPSAC’s mandatory role in FDA’s review of MRTP applications and its requirement that TPSAC provide FDA with “recommendations” on each application.

Nevertheless, the Voting Procedures Guidance is instructive for understanding FDA’s thinking as to when advisory committee votes generally are taken to provide committee recommendations to FDA. The guidance states that votes are not taken at some advisory committee meetings, such as “meetings to discuss the development of a clinical trial design or the development of a guidance document,” but “[a]t other advisory committee meetings, members cast a formal vote on issues related to the approvability of a product submission.”¹⁰ As discussed more fully below, in TPSAC’s review of MRTP applications during the period 2015-18, FDA asked the Committee to vote on a number of issues related to the authorization criteria for the subject MRTPs. However, more recently that practice has been

groups have filed multiple comments with FDA on this topic in recent years and incorporate those comments by reference: Comments by CTFK, et al., in Docket No. FDA-2014-N-0001, April 18, 2014 TPSAC meeting re modified risk tobacco products (April 2, 2014), available at <https://bit.ly/2HLvfON> (last accessed Oct. 2, 2020); Comments of CTFK in Docket No. FDA-2017-N-0001, April 6, 2017 TPSAC meeting re review of modified risk applications (March 22, 2017).

⁶ Available at <https://www.facadatabase.gov/FACA/FACAPublicCommittee?id=a10t0000001h1L3> (last accessed Oct. 2, 2020).

⁷ The Technical Project Lead (TPL) reports for MRTP orders both granted and denied thus far simply recite the statutory language that TPSAC reported its recommendations on the applications during an open public committee meeting held on the relevant date(s). The TPL reports provide no further clarification of what constitutes TPSAC’s “recommendations.” *E.g.* FDA, IQOS TPL Report, available at <https://www.fda.gov/media/139796/download> (last accessed Oct. 2, 2020).

⁸ FDA, Voting Procedures Guidance at 4, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voting-procedures-advisory-committee-meetings> (last accessed Oct. 2, 2020).

⁹ *Id.* at 3.

¹⁰ *Id.* at 4.

discontinued, and at no point has TPSAC reported recommendations as to its overall disposition of the applications themselves.

II. TPSAC’S ROLE IN EVALUATING MRTP APPLICATIONS HAS BEEN INAPPROPRIATELY MARGINALIZED OVER TIME AND TPSAC IS NOT PERFORMING THE ROLE GIVEN IT BY THE TCA

Five different sets of MRTP applications have been referred to TPSAC to date.¹¹ FDA sets the agenda for each TPSAC meeting, including identifying questions for the Committee to guide the Committee’s deliberations. A review of TPSAC meetings on MRTP applications supports the following observations, indicating that the Agency has set the agenda so that TPSAC has served merely as a discussion forum, rather than a body that provides recommendations to the Agency:

- Without explanation, in the last two years, FDA has reduced its voting questions for TPSAC to zero.¹² This is demonstrated by the table below.

TPSAC Meeting Date	MRTP Application Under Consideration	Number of Voting Questions
April 2015	Swedish Match’s general snus products	10
January 2018	Philip Morris Products’ IQOS system and Heatsticks	9
September 2018	RJ Reynolds’ Camel snus products	8
February 2019	1. Swedish Match’s general snus products ¹³ 2. Altria’s Copenhagen snuff	0 1
February 2020	22 nd Century Group’s very-low-nicotine cigarettes	0

- In its first three meetings to consider MRTP applications, FDA asked TPSAC to **vote** on important scientific issues regarding relative-risk determinations, the likelihood of changes in patterns of use among tobacco users and non-users, the likely potential users of the proposed MRTP, and consumer comprehension of modified risk information.¹⁴ More recently, FDA has asked TPSAC only to **discuss** these same issues without voting on them and without asking for any recommendations on the applications.

¹¹ The applications for Swedish Match’s general snus products have been referred to TPSAC twice, but we count them as one set. The original submission was referred to TPSAC in April 2015, and an amendment to the original submission was referred to TPSAC in February 2019.

¹² During one TPSAC meeting, Dr. Brian King from the Center for Disease Control and Prevention asked why there wasn’t any type of vote on the Swedish Match amendment, and Dr. Benjamin Apelberg from FDA responded that the Agency “felt what would be most useful was to really just have the qualitative discussion [because] it’s the richness of the discussion that’s really the most useful and informative.” February 6-7, 2019 TPSAC Meeting, Transcript from Day 1 at 139-40.

¹³ Amended application.

¹⁴ All questions to the Committee for all MRTP applications referred to TPSAC to date are provided in the Appendix.

- For four of the five products, FDA asked TPSAC to vote on one of the required authorization criteria in Section 911(g)—whether evidence substantiates the scientific accuracy of proposed modified risk claims¹⁵—but the Agency has stopped asking TPSAC to vote on other critical questions material to application of the public health standard for authorizing MTRPs, such as the likelihood of changes in patterns of use or consumer comprehension of modified risk information. FDA has not posed such questions to TPSAC since the second TPSAC meeting on an MRTP application in January 2018 when Philip Morris’ IQOS was the product under review.
- At no point has FDA asked TPSAC for its recommendations on the most important of all questions regarding the applications: whether to grant or deny MRTP orders based on the scientific evidence before the Agency.

In short, FDA has curtailed TPSAC’s ability to use its scientific expertise to provide FDA with a clear opinion on issues directly related to whether an application should be granted in the MRTP evaluation process. This is wholly inconsistent with Congress’ intent that FDA’s evaluation of MRTP applications include independent and transparent recommendations by TPSAC.

For TPSAC to fulfill its statutory role, it must go beyond general discussion where no conclusions or recommendations are reached and where the Committee is deprived of the ability to voice its views on the issues that determine the outcome of an MRTP application. Congress required TPSAC to be given the opportunity, indeed the obligation, to issue **recommendations** on critical aspects of each application, and that requires that FDA provide TPSAC the opportunity to vote on each scientific question necessary to be resolved for FDA to reach a decision on applications. Most importantly, by failing to vote on key scientific questions, TPSAC cannot establish a foundation from which to make recommendations on the application itself, as required by law.¹⁶

A comparison of the TPSAC meetings reviewing Philip Morris’ IQOS and 22nd Century’s very-low-nicotine (VLN) cigarettes illustrates the stark contrast between clear, specific, and actionable votes on important scientific questions, and general discussion of similar concepts. The voting questions posed to TPSAC about IQOS provided FDA, and the public, with the Committee’s assessment of the available scientific evidence on specific material issues. For example, TPSAC members overwhelmingly found it unlikely that consumers would completely switch to IQOS from conventional cigarettes and that there was a medium-high probability consumers would be converted into dual users.¹⁷ Committee members were

¹⁵ The four products include: (1) Swedish Match’s general snus at the April 2015 TPSAC meeting, (2) Philip Morris’ IQOS system and Heatsticks at the January 2018 TPSAC meeting, (3) RJ Reynolds’ Camel snus at the September 2018 TPSAC meeting, and (4) Altria’s Copenhagen snuff at the February 2019 TPSAC meeting. In the most recent February 2020 TPSAC meeting discussing 22nd Century Group’s very-low-nicotine cigarettes, FDA’s briefing document stated that its preliminary scientific review found the three proposed claims substantiated and that it was not seeking committee input on the seven additional, but similar-in-content, claims. Similarly, TPSAC was not asked to vote on Swedish Match’s amended application discussed at the February 2019 meeting.

¹⁶ Applications may also be amended or supplemented after TPSAC meetings, depriving TPSAC of the opportunity to consider all relevant data and undermining the Committee’s ability to fulfill its statutory duty to report its recommendations on the application.

¹⁷ *Supra* note 1, at 594.

also asked to concisely summarize the reasoning for their votes,¹⁸ providing FDA with a clear indication of TPSAC's views on each of the topics about which it was asked to vote. For example, following the first voting question on whether "scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases, Dr. O'Connor stated that he "had a problem with the linkage between scientific studies and human disease," Dr. Beirut said she did not "believe that the scientific evidence in humans exists at this point," and Dr. Huang concluded "the evidence [was] lacking" in terms of impact on human disease.¹⁹ The Technical Project Lead report accurately reflects these assessments, concluding that "most members stated that the lack of long-term human studies led them to conclude that a reduction in risk of tobacco-related disease had not been demonstrated."²⁰

Yet, at the latest TPSAC meeting where the VLN cigarettes applications were discussed, TPSAC was not asked to vote on any specific questions and no similarly clear conclusions emerged. The Committee was not asked—either as individual voting members or as a body—to provide any summary of its views or even state a position on the particular issues discussed. While some voting members took it upon themselves to make such remarks,²¹ these rare instances do not fulfill TPSAC's statutory obligation to report its recommendations on each application.

Finally, in defiance of Section 911(f)(2) of the FDCA, TPSAC was not asked, at either the IQOS meeting where votes were taken, or the VLN cigarettes meeting where the Committee served as merely a discussion forum, to provide its recommendation as to whether FDA should grant or deny the applications based on its scientific evaluation.

III. FDA SHOULD FULLY ENABLE TPSAC TO FULFILL ITS STATUTORY DUTY TO TIMELY REPORT ITS RECOMMENDATIONS ON MRTP APPLICATIONS

The modified risk proceedings of TPSAC are critical for gaining public and expert input and for transparency to enable the public to understand and evaluate the scientific merit of MRTP applications. The TCA also makes TPSAC more than a discussion forum. It gives it a legal mandate to evaluate the scientific evidence and offer its scientific assessments and recommendations to the FDA on the issues that the statute requires FDA to consider in making its decision. To enable the Committee to provide such recommendations, FDA must provide TPSAC with the opportunity to vote on each of the scientific issues that must be resolved to determine whether MRTP applications meet the statutory public health standard. In addition, TPSAC voting members should be instructed to vote on whether an application meets the scientific standards for granting the MRTP applications.

¹⁸ Immediately prior to calling the first vote in January 2018, TPSAC Chair, Dr. Huang, explained that, after every vote, "each member will state his or her name and vote into the record and reason you voted as you did." *Id.* at 524.

¹⁹ *Id.* at 526-27.

²⁰ *Supra* note 8. However, as noted *supra* at n.1, TPSAC's assessments apparently were disregarded by FDA in authorizing the reduced exposure claims for IQOS.

²¹ For example, Dr. Warner and Ms. Herndon expressed concern about the subject products' name change to Moonlight, and TPSAC Chair, Dr. Mermelstein, summarized the Committee sentiment that the name "VLN" is less concerning than Moonlight. February 14, 2020 TPSAC Meeting Transcript, at 16, <https://www.fda.gov/media/136252/download> (last accessed Oct. 2, 2020).

Respectfully,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Appendix

Date	MRTPA	FDA's Questions to the Committee
April 2015	Swedish Match's general snus products	<p>With respect to the relative health risks to individual users of these snus products (i.e., the Swedish Match North America, Inc. snus tobacco products that are the subject of these applications):¹</p> <ol style="list-style-type: none"> 1. Discuss the evidence regarding the association between the ten snus products and gum disease or tooth loss. Please address the following issues in your discussion. <ul style="list-style-type: none"> • Biological plausibility that gum disease or tooth loss in snus users would differ from those in users of other smokeless tobacco products; • Confidence in the information from studies that only include young adults under the age of 25, given that the prevalence of periodontal disease increases with age; • Confidence in the information on tooth loss from the use of snus, where the studies presented in the application evaluated the number of teeth between snus users and non-users in cross-sectional studies; • Sufficiency of information from studies where the number of snus users in many of the cross-sectional surveys was fewer than 50. <ol style="list-style-type: none"> a. Does the evidence support that these snus products <i>do not</i> pose risks of gum disease to individual users of these products? (vote) b. Does the evidence support that these snus products do not pose risks of tooth loss to individual users of these products? (vote) 2. Discuss the evidence regarding the association between these ten snus products and oral cancer. <ol style="list-style-type: none"> a. Does the evidence support that these snus products <i>do not</i> pose risks of oral cancer to individual users of these products? (vote) 3. Discuss the evidence regarding the association between the ten snus products and overall risks to health as compared to cigarettes. <ol style="list-style-type: none"> a. Should the comparison focus on the major smoking-related diseases according to population burden or assess all relevant health outcomes? (vote) b. Does the evidence support the statement that health risks to individual users from using these snus products <i>exclusively</i>, are “substantially lower” than the health risks from smoking cigarettes? (vote)

¹ Note: revisions made by the TPSAC appear in italics.

c. Does the *evidence support that* the proposed warning statement adequately communicates the potential health risks to individual users of these snus products? (vote)

4. Assuming that the behavior of U.S. population does mimic those in Sweden with respect to the use of snus, what information would the Committee need to know about the snus products that are used in Sweden and the snus products that are the subject of these applications in order to have confidence that the health outcomes observed in Sweden would also be observed in the U.S.?

For example, would it be sufficient to know that the exposures to individual users of the Swedish products are comparable to the exposures to individual users of these snus products, or would knowledge about other characteristics of the tobacco product be needed to determine that the health outcomes would likely be comparable?

With respect to the likelihood that existing users of tobacco products who would otherwise stop using those products will instead switch to these snus tobacco products, and the likelihood that persons who do not use tobacco products will start using these snus tobacco products:

5. Discuss the evidence regarding the likely impact of these ten snus products on tobacco use behaviors among tobacco users and non-users.
- a. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the:
 - i. The likelihood that current tobacco users in the U.S. will switch to the use of these snus products? (vote)
 - ii. The likelihood that non-users of tobacco in the U.S. will initiate the use of these snus products? (vote)
 - b. The applications did not include several types of studies that could be useful in order to assess impacts on behavior, such as actual use studies, self-selection studies, or other behavioral studies. Does the Committee believe that the applications include sufficient information on the behavioral aspects of the use of these snus products among the U.S. population? (vote)

With respect to enabling consumers to comprehend the modified risk information and understand its relative significance in the context of total health: (time permitting)

6. The applicant proposes to include modified risk information within a warning label. FDA has potential concerns that inclusion of information about relative benefits of product use within a warning label may raise additional questions regarding consumer comprehension of the modified risk information and perceptions of the product.

		<p>a. From the perspective of enabling consumers to understand the modified risk information in the context of total health, does the Committee believe it is appropriate to include modified risk information within the context of the required warning label as opposed to in a statement separate from, and in addition to, the warning label? (vote)</p> <p>With respect to postmarket surveillance and studies to be conducted by Swedish Match North America, Inc.: (time permitting)</p> <p>7. If FDA were to issue an order allowing the marketing of these snus products as modified risk tobacco products, what recommendations does the Committee have for postmarket surveillance and studies?</p> <p>a. What elements should Swedish Match North America, Inc. include in a postmarket surveillance and studies program in order to monitor product use transitions for these snus products, which may have a low prevalence of use?</p> <p>b. What methods does the Committee recommend that Swedish Match North America, Inc. employ for assessing the impact of a specific modified risk tobacco product marketing on perceptions and behavior in a postmarket setting, particularly among youth?</p> <p>c. What sources of data does the Committee recommend that Swedish Match North America, Inc. use for providing information on impacts resulting from the marketing of the products as modified risk tobacco products?</p> <p>d. What additional information does the Committee recommend that FDA request from the applicant regarding plans to conduct postmarket surveillance and studies?</p>
January 2018	Philip Morris Products' IQOS system and heatsticks	<p>1. Discuss evidence related to the health risks of the IQOS system and the appropriateness of the proposed modified risk information.</p> <p>a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases."? (Vote)</p> <p>b. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes."? (Vote)</p> <p>2. Discuss evidence related to human exposure to harmful or potentially harmful chemicals when combusted cigarette smokers completely switch to the IQOS system, including the implications of changes in exposure for long-term disease risk and the appropriateness of the proposed modified risk information.</p>

		<p>a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.”? (Vote)</p> <p>b. If the answer to question 2a is “yes”, has the applicant demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality? (Vote) <i>[To be answered by Committee members who voted “yes” to 2a.]</i></p> <p>3. Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the IQOS system, completely switch to IQOS, and/or become long-term dual users of IQOS and combusted cigarettes.</p> <p>a. What is the likelihood that that U.S. smokers would completely switch to use of the IQOS system? (High/Medium/Low)</p> <p>b. What is the likelihood that U.S. smokers would become long-term dual users of IQOS and combusted cigarettes? (High/Medium/Low)</p> <p>4. Discuss evidence regarding the likelihood that persons who do not use tobacco products will start using the IQOS system.</p> <p>a. What is the likelihood that U.S. never smokers, particularly youth, will become established users of the IQOS system? (High/Medium/Low)</p> <p>b. What is the likelihood that former smokers will re-initiate tobacco use with the IQOS system? (High/Medium/Low)</p> <p>5. Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising.</p> <p>a. Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of IQOS use as conveyed in the modified risk information? (Vote)</p> <p>b. What additional information, if any, needs to be communicated, other than what has been proposed by the applicant, for consumers to understand the health risks of the IQOS system?</p>
September 2018	RJ Reynolds’ Camel snus products	<p>1. The proposed modified risk claims that the applicant identifies as its “key” claims describe the reduction in risk for specific diseases as a result of completely switching to the six Camel Snus products from cigarettes.</p> <p>DISCUSS the available scientific evidence and VOTE on the extent to which the available scientific evidence substantiates the following modified risk information in the applicant’s advertising: “Smokers who switch completely from cigarettes to Camel SNUS can significantly reduce their risk of...”</p> <p>a. lung cancer? (yes/no/abstain)</p>

		<p>b. oral cancer? (yes/no/abstain) c. respiratory disease? (yes/no/abstain) d. heart disease? (yes/no/abstain)</p> <p>2. The applicant’s advertising also contains modified risk statements that describe a reduction in harmful chemicals in Camel Snus vs. cigarettes, or that are not as specific as those presented in Question 1 (e.g., do not reference reduction in specific diseases or the need for complete switching). All of these statements are being evaluated as part of the MRTPAs.</p> <p>DISCUSS the available scientific evidence and VOTE on the extent to which the available scientific evidence substantiates the following modified risk information in the advertising:</p> <p>a. “...Camel SNUS contains less of the harmful chemicals than cigarette smoke”? (yes/no/abstain) b. “Smokers who use Camel SNUS instead of cigarettes can significantly reduce their health risks from smoking.” (yes/no/abstain) c. “Switching to snus means less risk for you.” (yes/no/abstain) d. “NO SMOKE = LESS RISK” (yes/no/abstain)</p> <p>3. In addition to evaluating the proposed modified risk for scientific accuracy, FDA is also evaluating consumer understanding and perception of the modified risk information in the advertising. The applicant plans to communicate all of the modified risk information together, i.e., the first page has less specific modified risk information, while the second and third pages have more specific modified risk information and additional information the applicant refers to as “balancing information” (e.g., that Camel Snus and other tobacco products contain nicotine and are addictive; the recommendation that smokers concerned about the health risks of smoking should quit and talk to a healthcare provider).</p> <p>DISCUSS potential implications of the proposed modified risk information, including the non-specific modified risk language, as described in Question 2, on consumer understanding and perceptions and tobacco use behavior:</p> <p>a. Can the non-specific modified risk information be misinterpreted? b. Is there sufficient evidence that consumers would understand the non-specific modified risk information? c. Is there sufficient evidence about the impact of the non-specific modified risk information on the likelihood of use? d. Is there sufficient evidence about the impact of the non-specific modified risk information on poly tobacco use or partial switching?</p>
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		<p>4. DISCUSS the potential users of the proposed MRTPs.</p> <ul style="list-style-type: none"> a. What is the likelihood that cigarette smokers will switch completely to the six Camel Snus products? b. Are there other groups of potential users, particularly unintended users (e.g., youth, former cigarette smokers), of concern?
February 2019	<p>1. Swedish Match’s general snus products²</p> <p>2. Altria’s Copenhagen snuff</p>	<p>1. Swedish Match’s general snus products</p> <p>FDA’s preliminary assessment of the amendment finds that the applicant has addressed previous concerns by proposing a modified risk claim that is (a) more specific and (b) independent of the warning label; and by conducting a new consumer perception study that does not suffer from the methodological flaws of their original study.</p> <p>Q1: DISCUSS FDA’s preliminary assessment, including whether the revised modified risk claim raises new or additional concerns regarding the potential impact on: a. consumer understanding; and b. population health.</p> <p>2. Altria’s Copenhagen snuff</p> <p>Q1: The applicant proposed the following modified risk claim: “IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer.”</p> <p>DISCUSS the available scientific evidence and VOTE on the extent to which the proposed modified risk claim is scientifically accurate. (yes/no/abstain)</p> <p>Q2: In addition to evaluating the proposed modified risk claim for scientific accuracy, FDA also evaluates consumer understanding and perception of the modified risk information in the advertising.</p> <p>DISCUSS the potential implications of the proposed modified risk information on consumer understanding and perceptions.</p> <p>Q3: DISCUSS the potential users of the proposed MRTP.</p> <ul style="list-style-type: none"> a. What is the likelihood that cigarette smokers will switch completely to Copenhagen Snuff Fine Cut? b. Considering the health risks from the use of Copenhagen Snuff Fine Cut and those who may be likely to use the product, what are the groups of potential concern (e.g., users of smokeless tobacco products with lower HPHC levels, youth)?
February 2020	22 nd Century Group’s	1. Morbidity & Mortality. Discuss the likelihood that reductions in dependence translate into substantial reductions in morbidities and mortality among individual tobacco users.

² Amended application

	very-low-nicotine cigarettes	<p>2. Effect on Nonsmokers. Discuss the extent to which the following groups are likely to try and progress to regularly using the proposed MRTPs: Never smokers, Former smokers.</p> <p>3. Effect on Smokers. Discuss the extent to which the following groups will dual use the proposed MRTPs with their usual brand of cigarettes or exclusively use the proposed MRTPs: Cigarette smokers who want to quit smoking, Cigarette smokers who do not want to quit smoking.</p> <p>4. Understanding. Discuss whether the labeling enables consumers to accurately understand the following effects of using the products: Addiction risk, Disease risks.</p>
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