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1. EXECUTIVE SUMMARY

On July 5, 2023, Philip Morris Products S.A. (PMP S.A.) submitted applications seeking to renew the MRTP status of IQOS 2.4 System Holder, IQOS 3 System Holder, HEETS Amber, HEETS Blue, and HEETS Green.[1] For the IQOS products subject of the MRTPA renewal, FDA issued an Acceptance letter on September 5, 2023, and a Filing letter on May 9, 2024, classifying the products as Heated Tobacco Products (HTPs). The MRTPA renewal is currently pending substantive scientific review.

Part of the substantive scientific review phase involves full tobacco product unique identification. The purpose of unique identification is to explain what information is needed to identify and evaluate different types of products for full product characterization. Two of the properties required to establish unique identification include the product category and subcategory.

The recently updated March 24, 2025, PMTA orders changed the unique identification of IQOS products from non-combusted cigarettes to open HTPs and HTP consumables. However, the orders also included a footnote stating that FDA considered IQOS products to be cigarettes under section 900(3) of the FD&C Act and that cigarette products must comply with applicable provisions of the FD&C Act.[2,3]

While the MRTPA renewal is pending substantive scientific review, during which full tobacco product unique identification will be established, this amendment is submitted to (1) provide new evidence which demonstrates that IQOS products do not meet the statutory definition of a cigarette and (2) request removal of the required smoking-related warnings on IQOS consumables upon MRTP order issuance. This request is based on the following:

1. **IQOS consumables do not meet the statutory definition set forth in section 900(3) of the FD&C Act**.

   Section 900(3) of the FD&C Act defines "cigarette" as a tobacco product that is both (1) "a roll of tobacco wrapped in paper or in any substance not containing tobacco"; and (2) "includes tobacco, in any form that is functional in the product, which because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette."[4] Thus, whether a product meets the definition of a cigarette hinges on whether the product, because of its appearance, filler, packaging, and labeling, is likely to be marketed to, and perceived by, consumers as a cigarette. The appearance, filler, packaging, and labeling of IQOS consumables are all distinct from cigarettes. Moreover, PMI US does not market the IQOS

[1] Originally known as Marlboro *HeatSticks*®, Marlboro Fresh Menthol *HeatSticks*®, and Marlboro Smooth Menthol *HeatSticks*®, respectively
[2] Updated Marketing Granted Order Letters from FDA CTP to Philip Morris Products S.A. (STNs PM0000424.PD1-PM0000426.PD1 and PM0000479.PD1)
[3] Updated Marketing Granted Order Letters from FDA CTP to Philip Morris Products S.A. (STNs PM0000634.PD1)
[4] 21 U.S.C. § 387(3). *See also* 15 U.S.C. § 1332(1).

consumable as a cigarette and has developed evidence which demonstrates that consumers do not perceive the IQOS consumable to be a cigarette. Therefore, the product does not meet the statutory definition of a cigarette.

First, at a basic level, IQOS consumables are visually and physically distinct from a cigarette. They are considerably shorter in length than cigarettes. Further, IQOS consumables cannot be lit like a cigarette. They are not combusted like traditional cigarettes and are specifically designed to be used with the *IQOS* Holder – which heats tobacco rather than burning it.

Second, IQOS consumables have a unique filler. IQOS consumables have two significant parts: a tobacco part (tobacco plug) and a non-tobacco part. The tobacco part is made from a proprietary, reconstituted cast-leaf tobacco, which is designed to prevent combustion and is only for use with the IQOS Holder. The ingredients include ground tobacco, processed water, glycerin, guar gum, and cellulose fibers and the cast leaf is crimped from the bobbin during the manufacturing process. This design, including a significantly higher level of glycerin, is distinct from a cigarette.

Third, the packaging for IQOS consumables is different from cigarettes. The dimensions of the package are unlike a cigarette and the package itself would not be able to hold a cigarette.

Fourth, IQOS consumables are labeled and marketed differently than cigarettes. Specifically, IQOS consumables are expressly labeled as a "non-combustible product" and there is an explicit instruction on the pack that the "tobacco sticks" are "only for use with *IQOS* Originals." Indeed, the very claim language subject to this amendment demonstrates that IQOS consumables are intended to be marketed as distinct HTP consumables. In addition, IQOS consumables carry the warning "WARNING: This product contains nicotine. Nicotine is an addictive chemical." Cigarettes do not carry this warning.

Because of these fundamental differences, IQOS consumables are not likely to be offered to, or purchased by, consumers as a cigarette. Therefore, IQOS consumables are not a cigarette as defined in section 900(3) of the FD&C Act.

2. Product-specific evidence confirms that consumers do not perceive IQOS consumables to be cigarettes.

To better understand how U.S. legal age (i.e., ≥21 years old) current adult smokers (CAS) (n=1250) categorize IQOS within the context of the current tobacco and nicotine product (TNP) landscape in the U.S, we conducted a consumer perception study. Starting in November 2024 and completing in December 2024, the study was an online cross-sectional survey-based study with CAS recruited from

a probability-based nationally representative consumer panel, (b) (4) . A two-step weighting procedure was used to make the study population representative of 21+ U.S. CAS.

Virtually none of the participants classified IQOS products as cigarettes. Specifically, weighted study results show that, following exposure to an IQOS branded product image showing the device, holder, and *HEETS*® consumable, 0.0% (95% Confidence Interval (CI): 0.0% - 0.3%; unweighted n=1) of all participants classified IQOS as a cigarette. The study results also show that, following exposure to IQOS branded video showing the device, holder, *HEETS*® consumable, and *HEETS*® packaging, 2.3% (95% CI: 1.4% - 3.6%; unweighted n=25) of participants classified IQOS as a cigarette. Furthermore, following exposure to four HTP branded product images[5], only 1.6% (95% CI: 0.9% - 2.4%; unweighted n=19) of participants classified at least one as a cigarette. Finally, the study results also show that 98.0% of participants (95% CI: 96.7% - 98.9%, unweighted n=1228) correctly categorized all four cigarette branded product images[6] shown in the study.

This evidence demonstrates that consumers do not perceive the IQOS consumable as a cigarette. Therefore, because consumers are unlikely to perceive or purchase the IQOS consumable as a cigarette, it does not meet the statutory definition of a cigarette. Because the IQOS consumable is not a cigarette, the imposition of cigarette warning requirements on the IQOS consumable labeling would be contrary to law.

3. Imposing smoking-related warnings on IQOS consumables (which are classified by FDA as HTPs) is scientifically inaccurate and misleading to consumers.

Imposing cigarette warning requirements on the IQOS consumable labeling would be arbitrary and capricious and contrary to the Agency's public health mission, even if FDA takes the position that the IQOS consumable meets the statutory definition of a cigarette. Imposing warning requirements suggesting that the IQOS consumables have the same relative risk as the risks associated with smoking is inconsistent with FDA's own prior findings and the scientific evidence. This would mislead consumers, and would be contrary to sound public policy and our shared goal of moving adult smokers to products lower on the continuum of risk.

FDA's extensive scientific review supporting prior authorizations concluded that IQOS products do not produce smoke, and do not present the same risks as combusted cigarettes. The authorized modified risk claims reinforce differences compared to cigarettes by stating:

> "The IQOS system heats tobacco but does not burn it. This significantly reduces the production of harmful and potentially harmful chemicals. Scientific studies have

[5] IQOS, GLO, BONDS, PLOOM
[6] Camel, Marlboro, Newport, Lucky Strike

shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."[7,8]

Imposing requirements designed for cigarettes on IQOS consumables is not based on sound science and risks presenting inaccurate information to the public. Requiring smoking-related warnings for IQOS consumables suggests to consumers that IQOS products produce smoke and cause lung cancer, heart disease, emphysema, premature birth, fetal injury, and low birth weight. Yet FDA already concluded that they do not produce smoke, and there is insufficient evidence linking IQOS product use to cigarette-related risks and diseases. Therefore, the smoking-related warnings are entirely inconsistent with FDA's conclusion that IQOS products are appropriate for the protection of public health and its decision to authorize a modified risk claim stating that complete switching from conventional cigarettes to the IQOS system will significantly reduce exposure to harmful chemicals.

For all of these reasons, imposing these requirements on IQOS consumables lacks scientific merit and inevitably would mislead consumers to make incorrect assumptions about the risks of IQOS products and think that these products are equally as harmful as cigarettes. Specifically, the inclusion of these warnings on IQOS consumables is likely to lead consumers to mistakenly think that IQOS products produce smoke, are proven to cause the adverse health outcomes featured in cigarette warnings, and present the same health risks as combusted cigarettes, each of which are contradicted by FDA's own prior findings.

FDA has long acknowledged that nicotine, while addictive, is delivered through products on a "continuum of risk," which are most harmful when delivered through smoke particles created by combustion. FDA and PMI US share the goal of facilitating complete switching of adult smokers to products lower on the continuum of risk. FDA previously determined that IQOS products present a lower risk of tobacco-related harms than combusted cigarettes. In the Technical Project Lead review outlining the scientific rationale supporting previous authorizations, FDA concluded that "combusted cigarette smokers who switch completely to IQOS will have reduced toxic exposures and this is likely to lead to less risk of tobacco-related disease."[9]

It would impede FDA's goal of promoting awareness of the relative risks of tobacco products, if the Agency were to require smoking-related warnings on IQOS consumable packaging. The warnings would imply *more* harm or *greater* risk of disease from IQOS use compared to FDA's own conclusions from its review of available scientific evidence. Further, because they would present IQOS

[7] Modified Risk Grant Orders – Exposure Modification: MR0000059-MR0000061, MR0000133
[8] Modified Risk Granted Orders – Exposure Modifications Granted Letter from FDA CTP to Philip Morris Products S.A., IQOS 3 Device (MR0000192)
[9] See Page 11 of TPL Review for PM0000424.PD1-PM0000426.PD1, and PM0000479.PD1

consumables as having comparable risk to cigarettes, imposing these warnings on IQOS consumables would mislead consumers by suggesting that combusted cigarettes are associated with *less* harm or *lower* risk of disease than is actually the case.

4. The Administrative Procedure Act (APA) requires that FDA decisions be based on substantial evidence.

The APA requires that agency action be record-based and supported by substantial evidence, and FDA action is arbitrary and capricious if it fails to consider evidence bearing on the issue to be decided.[10] However, there is a lack of evidence to infer a causal relationship between IQOS product use and smoking-related risks and diseases. Thus, there is a lack of robust scientific evidence to substantiate combusted cigarette warnings for IQOS consumable labeling.

Were FDA to disregard its own factual findings and impose cigarette warnings on IQOS consumables which are, notably, classified by FDA as HTPs, FDA would require labeling that will mislead consumers regarding the available science of these products, which FDA has previously authorized as appropriate for the protection of public health and modified risk tobacco products. Continuing to impose combusted cigarette warnings on FDA-authorized IQOS consumables only delays efforts to transition current U.S. adult smokers down the continuum of risk and away from the most harmful form of tobacco.

For these reasons, imposing the smoking-related warnings required under the Federal Cigarette Labeling and Advertising Act (FCLAA) on IQOS consumables would be arbitrary and capricious.

2. BACKGROUND

The original Premarket Tobacco Product Application (PMTA) and Modified Risk Tobacco Product Application (MRTPA) orders issued on April 30, 2019, December 7, 2020, July 7, 2020, and March 11, 2022, preceded the PMTA Final Rule[11] and characterized the IQOS 2.4 System Holder, IQOS 3 System Holder, and HEETS Amber, HEETS Blue and HEETS Green[1] as non-combusted cigarettes. On November 4, 2021, the PMTA Final Rule went into effect, which created a new product category for HTPs. The PMTA Final Rule identified HTP consumables as a unique product category, describing HTP consumables as "comparable" or "similar" to a range of other product categories.[12]

Given this new classification, FDA updated the product category and subcategory of the IQOS 2.4 System and Holder, IQOS 3 System and Holder, and corresponding *HeatSticks*® in the original PMTA orders on

[10] *See Iaccarino v. Duke* 327 F. Supp. 3d 163, 175 (D.D.C. 2018). *See also*, *e.g.*, *Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010); *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009).
[11] Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300 (Oct. 5, 2021).
[12] *Id*. at 55,347.

March 24, 2025, and issued subsequent Acceptance and Filing letters on September 5, 2023, and May 9, 2024, subject of the MRTP Renewal applications to reflect the following:

Product name: IQOS 2.4 System Holder
Product category: Heated Tobacco Product (HTP)
Product subcategory: Open HTP

Product name: IQOS 3 System Holder
Product category: Heated Tobacco Product (HTP)
Product subcategory: Open HTP

Product name(s): HEETS Amber, HEETS Blue, HEETS Green[1]
Product category: HTP
Product subcategory: Consumable

As part of the updated unique identification table in the PMTA order letters, FDA also included the following footnote:

> "The IQOS products meet the definitions of cigarette in section 900(3) of the FD&C Act and components and parts in 21 CFR 1100.3 and 1141.3. Cigarettes and their components and parts must comply with the applicable provisions of the FD&C Act and regulations. For purposes of scientific review, the product category and subcategory have been revised."[13]

Section 900(3) of the FD&C Act defines the term "cigarette"—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term "cigarette" in section 1332(1) of title 15; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

With that consideration, PMI US agrees that IQOS products meet the following criteria:

Section 900(3)(A)(i): IQOS products are made or derived from tobacco and intended for human consumption, and thereby, are considered tobacco products.

Section 900(3)(A)(ii): IQOS products do contain a roll of tobacco wrapped in paper.

Section 900(3)(B): IQOS products include tobacco, in any form, that is functional in the product.

[13] Footnote was not included in the September 5, 2023, Acceptance or May 9, 2024, Filing letters

However, PMI US believes the administrative record, including new information presented in this amendment, demonstrates that IQOS products do not meet the following criterion:

> **Section 900(3)(B):** IQOS products, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, are likely to be offered to, or purchased by, consumers as a cigarette.

As discussed above, the IQOS consumable, because of its appearance, filler, packaging, and labeling, is unlikely to be offered to, or purchased by, consumers as a cigarette. This conclusion is confirmed by product-specific evidence. For these reasons, the IQOS products do not meet the statutory definition of a "cigarette" and therefore, should not be subject to requirements specific to cigarette products.

3. CONSUMER PERCEPTION STUDY

We conducted an online cross-sectional survey in November and December 2024 among U.S. Current Adult Smokers (CAS) ages 21 to 80 years old (median age: 53 years old) recruited from a probability-based nationally representative consumer panel, (b) (4) .[14] Prior to the implementation of study procedures and the start of data collection, an exempt status was obtained from the Advarra Institutional Review Board (IRB). By exposing study participants to branded product images for cigarettes, nicotine pouches, e-cigarettes, and HTPs, we measured the proportion of participants who classify:

- IQOS as a cigarette following exposure to an IQOS branded product image
- IQOS as a cigarette following exposure to an IQOS branded video
- Heated Tobacco Products (HTPs) as a cigarette following exposure to HTP branded product images
- Cigarettes, nicotine pouches, and e-cigarettes correctly following exposure to branded product images

A two-step weighting procedure was used to make the final study population representative of 21+ U.S. CAS per benchmarks provided by the National Health Interview Survey.

All supporting consumer perception study materials can be found in (b) (4) .[15]

IQOS product classification following exposure to an IQOS branded product image

Following exposure to an IQOS branded product image showing the device, holder, and *HEETS*® consumable, a total of 0.0% (95% CI: 0.0%-0.3%) of participants classified IQOS as a cigarette. At the

[14] (b) (4)
[15] (b) (4)

same time, 70.8% (95% CI: 67.7%-73.7%) of participants did not classify IQOS as a cigarette and 29.2% (95% CI: 26.3%-32.2%) responded 'I don't know' (see Figure 1).

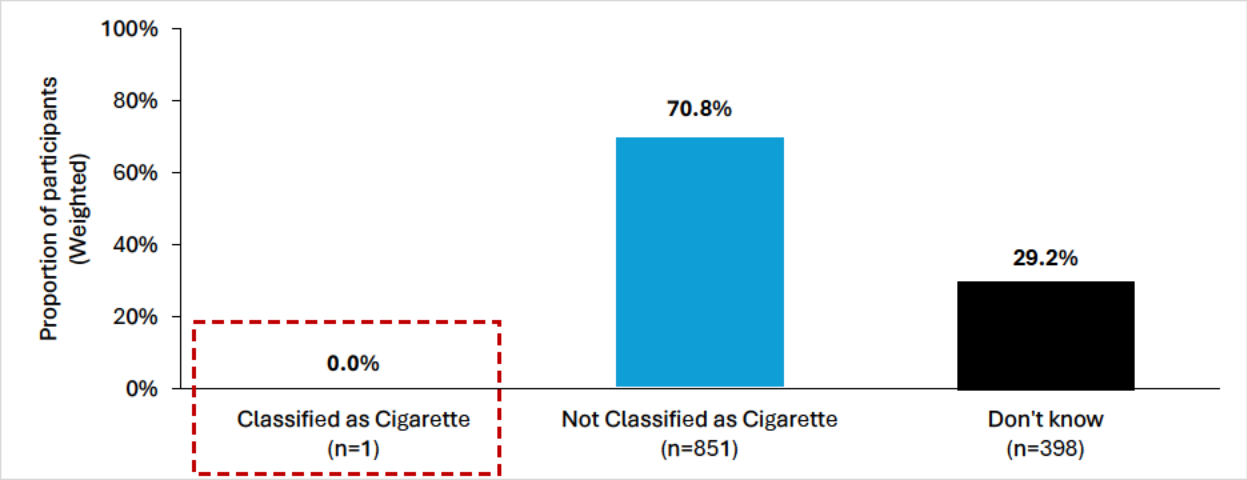


Figure 1. IQOS classification following exposure to an IQOS branded product image.

IQOS product classification following exposure to an IQOS branded video

Exposure to an IQOS branded video is of particular interest considering that all IQOS products currently sold in the U.S. are accompanied by a coaching experience that exposes current adult smokers to a video and/or hands-on experience showing IQOS operation of use. Additionally, the IQOS branded video exposed participants to the packaging of *HEETS*®, which was not shown as part of the IQOS branded product image but is a key element in the section 900(3) cigarette definition.

Following exposure to an IQOS branded video, a higher proportion of participants classified IQOS as a cigarette (2.3%, 95% CI: 1.4%-3.6%) compared to participants who classified IQOS as a cigarette following exposure to an IQOS branded product image, though both results were low overall. Notably, following exposure to an IQOS branded video, 81.1% (95% CI: 78.4% - 83.6%) of participants did not classify IQOS as a cigarette, and 16.6% (95% CI: 14.2% - 19.1%) responded as 'I don't know' (see Figure 2).

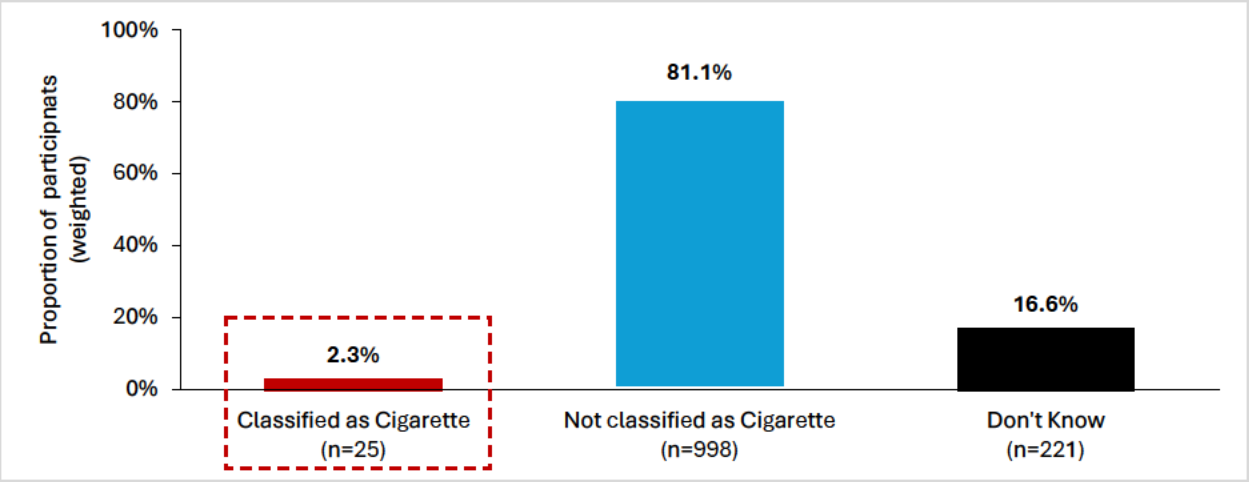
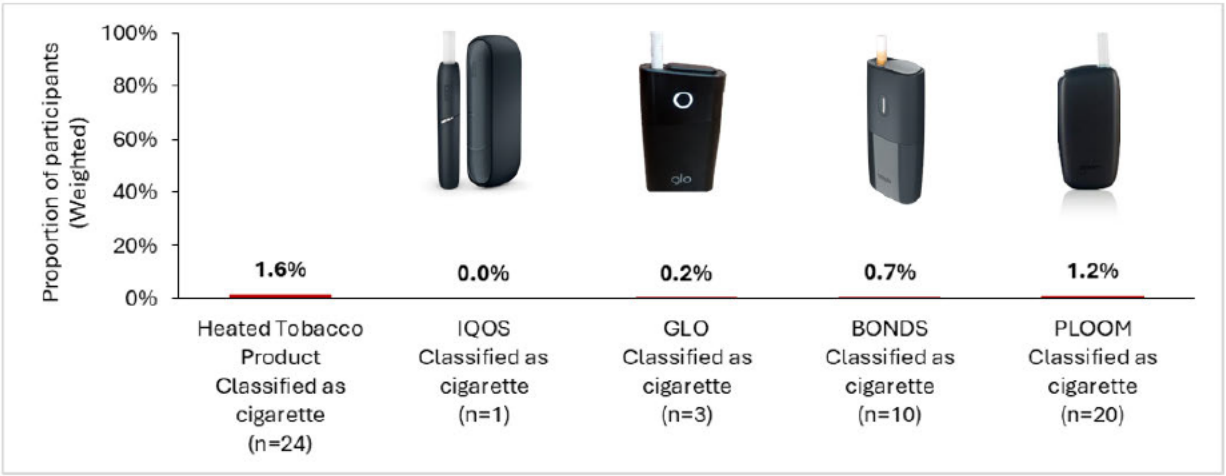


Figure 2. IQOS classification following exposure to an IQOS branded video.

Product classification following exposure to HTP branded product images

Following exposure to IQOS, GLO, BONDS, and PLOOM branded product images, the proportion of participants who classified at least one as a cigarette was overall low (1.6%, 95% CI: 0.9% - 2.4%). The majority of participants (82.8%, 95% CI: 80.2% - 85.2%) did not classify any HTP as a cigarette[16], and 15.6% (95% CI: 13.3% - 18.2%) of participants stated 'I don't know'[17]. Overall, the proportion of participants classifying the HTP as a cigarette was 0.0% (95% CI: 0.0% - 0.3%) for IQOS, 0.2% (95% CI: 0.0% - 0.6%) for GLO, 0.7% (95% CI: 0.3% - 1.3%) for BONDS, and 1.2% (95% CI: 0.7% - 2.0%) for PLOOM, respectively (see Figure 3).



[16] With up to three "I don't know" responses or up to one missing response.
[17] A participant was designated as having a 'I don't know' response if the participant selected 'I don't know' for all product images with up to one missing response allowed.

Figure 3. Product classification following exposure to HTP branded product images.

Product classification following exposure to Cigarettes, Nicotine Pouches, and E-cigarettes / Vapes branded product images

In total, 98.0% (95% CI: 96.7% - 98.9%) of participants correctly classified four cigarette branded product images[6], while this proportion reached 81.8% (95% CI: 79.3% - 84.2%) for four nicotine pouches branded product images[18], and 40.9% (95% CI: 37.6% - 44.3%) for five e-cigarettes/vapes branded product images (see Figure 4)[19]. A participant was designated as having a 'Correct' response if all respective branded product images were allocated to the correct product category.

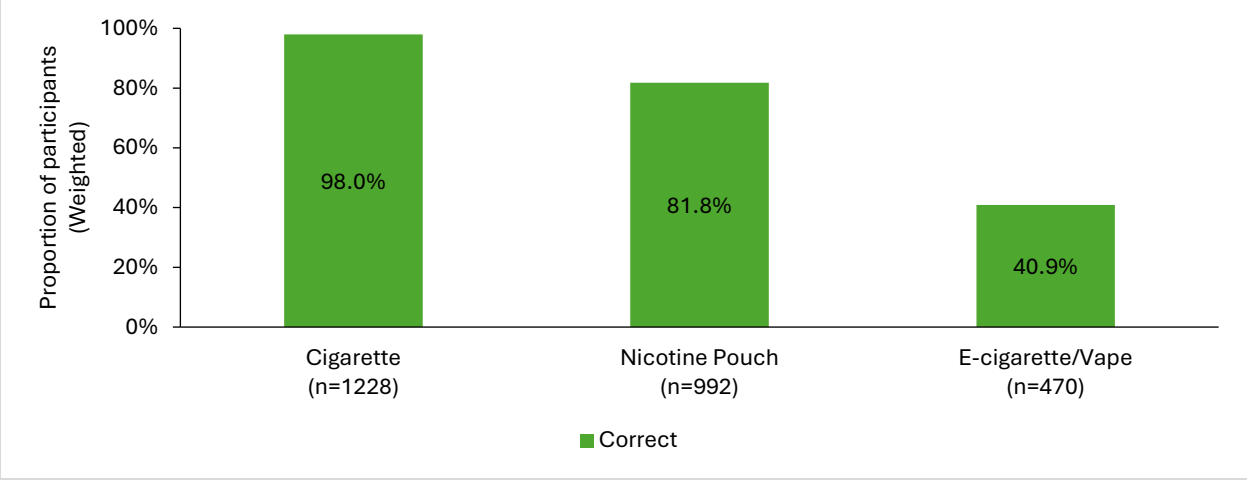


Figure 4. Product classification following exposure to Cigarettes, Nicotine Pouches, and Vapes branded product images.

Summary

Despite HTPs being a novel product category in the U.S., when participants were exposed to an IQOS branded product image showing the device, holder, and *HEETS*®consumable, 0.0% classified IQOS as a cigarette. Similarly, when participants were exposed to an IQOS branded video showing the device, holder, *HEETS*® consumable, and packaging, 2.3% classified IQOS as a cigarette.

The consumer perception study data shows that current adult smokers do not consider IQOS products to be cigarettes. Therefore, IQOS products do not align with the cigarette definition criteria set forth in

[18] ROGUE, ZYN, VELO, ON!
[19] Lost Mary, EB Design, JUUL, VUSE, SMOK

section 900(3)(B). For this reason, imposing cigarette-specific warning requirements on IQOS products would be inappropriate and contrary to law.

4. CONCLUSION

Available evidence demonstrates that the IQOS products do not meet the statutory definition of a cigarette and, therefore, should not be subject to cigarette-specific requirements. Rather, the products should be subject to requirements applicable to other categories of tobacco products, including the *nicotine is addictive* warning requirement. Although PMI US is confident that the available evidence conclusively demonstrates that the IQOS products are not cigarettes, if FDA were to reach a different conclusion, the evidence nonetheless demonstrates that imposing warnings designed for combusted cigarettes is arbitrary and capricious and does not protect public health.

Available evidence demonstrates that IQOS products are lower on the continuum of risk and do not present the same risks as combusted cigarettes, as confirmed by FDA's own findings. Upon review of the extensive clinical and non-clinical scientific evidence provided, FDA previously authorized the following modified risk reduced exposure claims for IQOS products:

1. The IQOS system heats tobacco but does not burn it.
2. This significantly reduces the production of harmful and potentially harmful chemicals.
3. Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.

Were FDA to disregard its own factual findings and impose combusted cigarette warnings on IQOS consumables, which are classified by FDA as HTPs, FDA would mislead consumers regarding the available science of these products for which FDA has previously authorized as appropriate for the protection of public health and modified risk. Additionally, the inclusion of these warnings on IQOS consumables is likely to lead consumers to mistakenly think that IQOS products produce smoke, are proven to cause the adverse health outcomes featured in cigarette warnings, and present the same risks as combusted cigarettes. For the reasons discussed herein, we request removal of the required smoking-related warnings from IQOS consumables. We remain committed to ensuring that IQOS consumable labeling contains the *nicotine is addictive* warning conditioned in the April 29, 2019, PMTA TPL review.[20]

[20] See Page 87 of TPL Review for PM0000424.PD1-PM0000426.PD1 and PM0000479.PD1