PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Noah Joshua Phillips
Rebecca Kelly Slaughter
Christine S. Wilson
Alvaro Bedoya

In the Matter of **Altria Group, Inc.** **a corporation;** **and** **JUUL Labs, Inc.** **a corporation.**	**DOCKET NO. 9393**

RESPONDENTS' RESPONSE TO COMPLAINT COUNSEL'S SECOND MOTION REQUESTING OFFICIAL NOTICE OF FDA DECISION

The Commission stated that it will defer determination as to "what inferences, if any, to draw" about the materiality of FDA's Premarket Tobacco Application ("PMTA") authorizations until after considering the "full briefing and oral argument[ation] that will accompany Complaint Counsel's appeal." Order at 2, No. 9393 (May 13, 2022). Complaint Counsel ("CC") now seeks official notice of the latest of FDA's rolling PMTA authorizations, this time for RJ Reynolds' Vuse Ciro and Vuse Vibe cig-a-like products containing nicotine salts ("FDA's Decision"). CC contends these authorizations are material because they supposedly "reinforce[] [CC]'s argument that but for the transaction, Altria would have been a competitively significant player in the closed-system e-cigarette market." CC's Second Motion Requesting Official Notice of FDA Decision ("CC's Second Motion") at 1, 4, 5-6.

As Respondents previously set out, to the extent the Commission ultimately considers FDA's PMTA authorization decisions years later as "impli[cating the] PMTA approval prospects" of Altria's products, Order at 2, No. 9393 (May 13, 2022), the authorizations to date

only confirm the improperly speculative nature of this inquiry and the proper bases of the judgment by Altria's scientists and regulatory personnel that Altria's products were unlikely to do so. Respondents' Motion for Official Notice of Recent FDA Decisions ("Respondents' Motion") at 1-2. Thus, while "Respondents do not contest the accuracy of [CC's] proffered records" (Order at 2, No. 9393 (May 13, 2022)), or oppose the Commission taking official notice of FDA's Decision, Respondents do contest CC's claims as to materiality and submit this response to address CC's mischaracterizations of the record and the Court's decision. As set forth below, CC is improperly using the notice process regarding FDA's PMTA authorizations to rehash arguments made and rejected by the Court and to make new arguments without any basis in the record.

Competitive Significance. CC's primary claim of materiality is that the authorization of these two cig-a-like products demonstrates that "but for the transaction, Altria would have been a competitively significant player in the closed-system e-cigarette market." CC's Second Motion at 6. There is simply no justification for this leap. Cig-a-likes were, at the time of the transaction, a minor part of the closed-system e-cigarette market CC describes, and are even less competitively relevant today. IDF178, 963-73. Altria removed its non-traditional flavored cig-a-like products from the market at the express suggestion of FDA months before the transaction, and FDA eventually ordered all such products off the market. IDF646-53.[1] No e-cigarette manufacturer would be a "competitively significant player" with just a cig-a-like product. Reynolds, which sales volumes for Vuse Solo fell off a cliff in 2018 and 2019 (IDF972), certainly would not be. As a Reynolds executive testified, pods are substantially more popular than cig-a-likes, IDF972, and Reynolds recognized in 2018 that "it needed a pod product to compete with JUUL," PX7037 Huckabee (Reynolds) Dep. 131:24-32:2. Reynolds thus launched

[1] CC is flatly wrong when it suggests in its motion that Altria withdrew only pod-based devices in response to FDA's September 12, 2018 call for action by e-vapor manufacturers. Altria also announced the removal of its non-traditional flavored cig-a-like products in the same publicly released letter to FDA (IDF650).

its Vuse Alto pod product, which has enjoyed significant success in the marketplace and overtaken JUUL in device share. IDF986, 999-1011.

To overcome these basic market facts, CC claims Judge Chappell based his determination that "Altria was not competitively significant" in e-vapor "*almost entirely* on [the] conclusion that Altria's products lacked conversion potential and would therefore have been unlikely to receive PMTA approval." CC's Motion Requesting Official Notice of FDA Decision ("CC's Motion") at 5 (emphasis added); *see also* CC's Second Motion at 5. Not so. The Court deemed Altria's products competitively insignificant because cig-a-likes, which represented more than 90 percent of Altria's cartridge sales volume, were drastically declining. ID96-97. "The record presents no reasonable basis for concluding that the MarkTen cig-a-likes would have been a stronger competitive force in the near future, capable of affecting price, output innovation, or shelf space competition." ID108 n.35. As for Altria's existing pod product, MarkTen Elite, putting aside that there is absolutely no dispute that it could not have obtained a PMTA, IDF317, 380-85, 573, the Court also found it competitively insignificant, observing that "the notion that a product with a market share of less than one percent could be a significant competitive constraint is illogical," ID97.[2]

In any event, the Court already took into account FDA's authorization of Vuse Solo, RJ Reynolds' primary cig-a-like product containing nicotine salts. That FDA authorization was issued before the completion of post-trial briefing, was remarked upon by the Court in its decision, and had no effect on the Court's determination that Complaint Counsel failed to prove anticompetitive effects. IDF261. That two additional Reynolds cig-a-likes products have now been approved does not change that assessment. Respondents' Motion at 7 n.3. Notwithstanding CC's repeated efforts to confuse the issue, PMTA authorization is not tantamount to commercial success or commercial viability. It is simply a regulatory prerequisite to being on the market. The record is overwhelming that an e-vapor product with the right

[2] The Court also held that Altria removed the products for independent business reasons. ID63.

formulation of nicotine salts is critical to a product's competitiveness and that Altria and its scientists—whose credibility has never been questioned—had that realization well before the transaction with JLI. ID80 (identifying "nicotine salts [as] the key ingredient to an e-vapor product's *commercial* success" (emphasis added)); IDF431-82 (setting forth Altria's realization in 2018 that all of its products either entirely lacked this key ingredient or effectively so); Tr. 34:12-17 (CC conceding during its opening statement that the "inclusion of nicotine salts" was "one key aspect" to JUUL's commercial success).

Regulatory Prospects. Notwithstanding CC's insistence that "official notice is not a vehicle to engage in interpretation or inference,"[3] CC uses this notice to do precisely that, arguing the approval of Vuse Vibe and Vuse Ciro means it is likely MarkTen Bold (Altria's single cig-a-like with some amount of salts) would have succeeded on its PMTA. According to CC, MarkTen Bold was "nearly identical to Vuse Vibe and Vuse Ciro" because "all three are cigalike products … contain nicotine salts." CC's Second Motion at 5. Again, not so—these are very different products. Vuse Vibe was acquired by RJ Reynolds to serve as Reynolds' cig-a-like with "the largest capacity cartridge and the longest-lasting battery," with a 3% nicotine formulation, IDF121; RFF243, and Vuse Ciro was designed to have a lower nicotine formulation, at 1.5%, but "maximum puff duration . . . significantly longer than that of [Vuse Solo]," to have "no limit on the number of puffs per cartridge," and to be "unique among [Vuse] products in that it can be charged from either end," PX8008 Huckabee (Reynolds) Decl. ¶ 18. MarkTen Bold, meanwhile, had an entirely different nicotine formulation. IDF458-68. And, like all of Altria's products, it emitted formaldehyde at levels higher than other e-vapor products and at levels that Altria believed FDA was unlikely to accept. IDF398-408. As FDA's disparate treatment of the myBlu (PMTA denied) and NJOY Ace (PMTA granted) pod-based nicotine salt products demonstrates, sharing the same product format and containing nicotine salts does not

[3] CC's Response to Respondents' Motion for Official Notice of Recent FDA Decisions ("CC's Response") at 4.

make two products nearly identical for purposes of FDA authorization. Respondents' Motion at 6-7.

In seeking to minimize the significant issues with Altria's existing products, CC, which chose to offer no expert testimony on the subject of FDA approval prospects, assumes the "scientific expertise" that Congress determined "[n]either the Federal Trade Commission nor any other Federal agency except [FDA]" possesses. Pub. L. No. 111-31, §2(45), 123 Stat. 1776, 1781 (2009). Thus, CC argues without basis that the "formaldehyde" issue is an "exaggerat[ion]." CC's Response at 6 n.4.[4] But there is no dispute that formaldehyde is a carcinogen, that Altria's products, including MarkTen Bold, emitted it at levels similar to cigarettes and greater than other e-vapor products, and that implications for public health are the lynchpin of FDA's PMTA analysis. *See* IDF398-412.[5]

As for conversion, a clear consideration for approval (*e.g.*, CC's Second Motion at 2 (acknowledging that "FDA looks at . . . conversion potential" in "making its PMTA determinations.")), CC has switched its tune, once again demonstrating the speculative nature of its exercise. It claimed in its opening merits brief that "a product without nicotine salts may [in fact] be *more likely* to win PMTA approval," OB22 (emphasis added). But within a matter of

[4] That Howard Willard, might have "seem[ed]" like he was not concerned about the issue in early March of 2018, PX1223 (dated Mar. 6, 2018), when he thought Altria might have a solution, does not change what he believed later when he learned the problem *could not* be resolved for the product in the market, and that there was no sense as to when or if it would be resolved for use in a new product, given continuing issues with the BVR 2.8 new battery design that would require separate PMTA authorization before it could be launched, *see* IDF401, 405-10, 682-86.

[5] CC also now implies that e-vapor products are not compared to one another in connection with the PMTA's appropriate for the protection of the public health analysis. CC's Response at 5-6. This point was undisputed below (CC's Reply Findings of Fact ¶80), and for good reason: the final PMTA rule requires "each PMTA to compare the health risk of its product to other tobacco products in the same product category" and makes clear that FDA considers that comparative information in assessing whether a product is appropriate for the protection of the public health because it contributes to FDA's "full understanding of the potential risks and benefits." 86 Fed. Reg. 55300-01, 55359-60 (emphasis added); *see also* RX2021 (FDA Draft Guidance Presentation, May 2016).

weeks, FDA approved three other products containing nicotine salts, and rejected one, culminating in a record whereby virtually every product FDA authorized to date contains some variation of nicotine salts.

As the Court noted, and as CC previously acknowledged in post-trial briefing, "any predictions about which products will or will not receive PMTA approval [are] highly speculative." ID108 (quoting Complaint Counsel Post-Trial Reply Brief at 122 n.62). The record is overwhelming that Altria's scientists and regulatory personnel, none of whom were involved in the deal negotiations, concluded that Altria's products were unlikely to succeed on a PMTA (IDF380-85, 541, 573, 593) and nothing about the recent authorizations supplies any basis to question that assessment which took into account the very factors FDA is now using.[6] CC's suggestion that Altria should have left its products on the market despite having concluded that they were likely not going to be authorized ignores not only their poor commercial performance but both the significant cost of preparing an application (IDF235-41) and the fact that other companies in fact only pursued those applications they believed had a chance at success (Respondents' Motion at 4).[7] It is also not disputable that it would be years (if ever) before any new, potentially more competitive product, could be on the market given the regulatory scheme.

[6] FDA recently granted public access to the PMTA denial letter it issued in connection with the myBlu application. As Respondents' forthcoming motion for official notice of this document will further highlight, the letter reflects that FDA denied the myBlu application based on some of the same issues Altria faced with its products.

[7] It is also a remarkable position for a government agency. The notion that Altria should keep on the market products it had determined were unlikely to be found by FDA as "appropriate for the protection of the public health" stands in stark contrast to the FTC's concerns stated elsewhere about protecting consumers who use these products. Lina Khan, *Remarks of Chair Lina M. Khan Regarding the Federal Trade Commission E-Cigarette Report for 2015-2018*, FTC (Mar. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Chair-Khan-Remarks-on-the-FTC-E-Cigarette-Report-for-2015-2018.pdf; Fed. Trade Comm'n, *E-Cigarette Report for 2015-2018* (Mar. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/E-Cigarette-Report-2015-2018.pdf.

Finally, CC claims Respondents cherrypick which FDA decisions should be noticed. Not true. Respondents opposed notice of FDA's decision regarding certain Logic products because Respondents were denied an opportunity to develop a record about the features of those products. *See* Respondents' Motion at 1-2. This does not apply to FDA's decisions regarding NJOY Ace and myBlu, which Respondents put forth, and likewise FDA's Vuse Ciro and Vuse Vibe authorizations, which Respondents do not oppose the Commission noticing. The opportunity to develop a record with respect to these products allowed Respondents to elicit that their respective manufacturers similarly looked to invest in a PMTA for products that they believed could obtain authorization. *E.g.*, Respondents' Opposition to CC's Motion Requesting Official Notice of FDA Decision at 1-2; Respondents' Motion at 4; RFF1096.

CONCLUSION

For the reasons set forth above, Respondents submit this response for the Commission's consideration.

Dated: June 3, 2022

Respectfully submitted,

By: *s/* David I. Gelfand
David I. Gelfand
Jeremy Calsyn
Matthew I. Bachrack
Linden Bernhardt
Jessica Hollis
Cleary Gottlieb Steen & Hamilton LLP
2112 Pennsylvania Avenue, NW
Washington, DC 20037
Telephone: (202) 974-1500

Counsel for Juul Labs, Inc.

By: *s/* Beth Wilkinson
Beth Wilkinson
James Rosenthal
Wilkinson Stekloff LLP
2001 M Street NW, 10th Floor
Washington, DC 20036
Telephone: (202) 847-4000

Moira Penza
Ralia Polechronis
Wilkinson Stekloff LLP
130 West 42nd Street, 24th Floor
New York, NY 10036
Telephone: (212) 294-8910

Jonathan M. Moses
Kevin S. Schwartz
Adam L. Goodman

Wilfred T. Beaye, Jr.
Wachtell, Lipton, Rosen & Katz
51 West 52nd Street
New York, NY 10019
Telephone: (212) 403-1000

Counsel for Altria Group, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2022, I caused a true and correct copy of the foregoing to be filed electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

Stephen Rodger (srodger@ftc.gov)
James Abell (jabell@ftc.gov)
Peggy Bayer Femenella (pbayer@ftc.gov)
Erik Herron (eherron@ftc.gov)
Joonsuk Lee (jlee4@ftc.gov)
Meredith Levert (mlevert@ftc.gov)
Kristian Rogers (krogers@ftc.gov)
David Morris (dmorris1@ftc.gov)
Michael Blevins (mblevins@ftc.gov)
Michael Lovinger (mlovinger@ftc.gov)
Frances Anne Johnson (fjohnson@ftc.gov)
Nicole Lindquist (nlindquist@ftc.gov)
Jeanine Balbach (jbalbach@ftc.gov)
Steven Wilensky (swilensky@ftc.gov)
Eric M. Sprague (esprague@ftc.gov)
Federal Trade Commission
400 7th Street, SW
Washington, DC 20024

Complaint Counsel

s/ Beth Wilkinson

Beth Wilkinson
Counsel for Altria Group, Inc.