UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

COMPLAINT COUNSEL'S RESPONSE TO RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF RECENT FDA DECISIONS

On May 16, 2022, Respondents filed a motion requesting that the Commission take official notice of the FDA's recent decisions to (1) deny Premarket Tobacco Application ("PMTA") authorization to Fontem US, LLC for several myBlu e-cigarette products, and (2) grant PMTA authorization for several NJOY Ace e-cigarette products.[1] Complaint Counsel does not oppose Respondents' motion, but respectfully files this response to rebut certain deficiencies and mischaracterizations contained in Respondents' motion. While Complaint Counsel agrees that the recent FDA decisions are appropriate for official notice, Respondents'

[1] Respondents neglect to request that the Commission take official notice of the FDA's May 12, 2022, decision to grant PMTA authorization to certain Vuse-branded cigalike products sold by R.J. Reynolds Vapor Company. This recent FDA decision is the subject of a separate motion for official notice filed by Complaint Counsel concurrently with this response. *See* Complaint Counsel's Second Motion Requesting Official Notice of FDA Decision, dated May 24, 2022.

motion (1) draws an artificial distinction between the FDA's recent decisions concerning myBlu and NJOY Ace products, and the FDA's prior decision on JTI's Logic products, and (2) impermissibly asks the Commission to draw unsupported inferences in Respondents' favor. These flaws are detailed further below.

A. Respondents' Motion is Inconsistent with Respondents' Previous Position and Seeks to Relitigate an Issue Already Remedied Before the ALJ

Respondents' motion is highly suspect given their previous position regarding official notice in this matter. Just six weeks ago, Respondents opposed Complaint Counsel's motion for official notice of the FDA's decision regarding JTI's Logic products. *See* Resps.' Opp. To CC's Mot. Official Notice (Apr. 7, 2022). Respondents' present motion asks the Commission to draw an unprincipled distinction: take notice of the FDA decisions that Respondents believe support their defenses while excluding the FDA decisions Respondents know support Complaint Counsel's claims.

Respondents argue that the Commission should not take official notice of the FDA's Logic decision because Complaint Counsel "denied Respondents the opportunity to develop a record about Logic products." Resps.' Mot. at 2. This is both inaccurate and a red herring. Complaint Counsel did not deny Respondents the opportunity to depose an executive from JTI. Complaint Counsel provided a copy of the declaration it had obtained from a JTI executive to Respondents on May 8, 2020, yet Respondents did not serve Complaint Counsel with a notice of the declarant's deposition until January 13, 2021. CC's Opp. to Resps.' Motion *In Limine* to Exclude a Declaration and Witness (Apr. 30, 2021) at 2. Due to travel restrictions occasioned by the pandemic and the declarant's location in Switzerland, Respondents were unable depose the JTI declarant before the close of fact discovery. *Id.* Respondents already received their remedy—the JTI declaration did not come into evidence.

In any event, the issue of Respondents' inability to depose an executive from JTI is both irrelevant and moot. The issue of official notice of the FDA's decision to approve certain Logic products is separate and distinct from any perceived prejudice to Respondents due to their inability to depose an executive from JTI who had provided a declaration in this case. Indeed, neither the Commission official notice rule nor the federal judicial notice rule require that the party opposing notice receive an opportunity for cross-examination. *See* 16 C.F.R. § 3.54; FRE 201. Respondents do not dispute that the FDA's Logic decision satisfies the requirements for official notice nor can they. Furthermore, this issue was litigated before the ALJ and any potential harm to Respondents was remedied by the ALJ's decision to exclude the JTI declaration from the record. *See* Order Granting Resps.' Motion *In Limine* to Exclude a Declaration and Witness (May 5, 2021).

Moreover, no cross-examination of a JTI witness is necessary for the Commission to understand the import and materiality of the FDA's decision approving certain Logic products. As set forth in Complaint Counsel's motion, the ALJ credited Respondents' arguments that Altria's existing e-cigarette products were unlikely to obtain FDA approval due to their form factor (for its cigalikes) and lack of nicotine salts (for both its cigalikes[2] and the MarkTen Elite pod product). CC's Mot. at 5-6. As set forth in Respondents' own Findings of Fact, the Logic Power is a cigalike that does *not* contain nicotine salts, while the Logic Pro is a hybrid device that also does *not* contain nicotine salts. Resps.' Proposed Findings of Fact ¶¶ 262, 1332. Thus, the FDA's approval of these Logic products directly undermines Respondents' contention that cigalike products and products without nicotine salts are incapable of obtaining FDA approval.

[2] Altria's MarkTen Bold cigalikes contained nicotine salts, but its other cigalikes did not. CCFF ¶¶ 129-130, 135.

No further "develop[ment] of the record" is necessary to establish the materiality of the FDA's approval of the Logic products.

B. Respondents' Motion Asks the Commission to Draw Unsupported Inferences Based on an Incomplete and Misleading Reading of the FDA's Press Releases

Complaint Counsel further objects to the unsupported inferences Respondents ask the Commission to draw and to Respondents' incomplete and misleading characterization of the FDA's press releases. While official notice may properly be taken of *facts* that are generally considered reliable and that have a guarantee of trustworthiness, official notice is not a vehicle to engage in interpretation or inference. *See In re Rambus Inc.*, No. 9302, 2003 WL 22064718, at *2 (F.T.C. Aug. 27, 2003) (limiting official notice to existence of patent and information contained on the face of the patent).

Respondents claim that the recent FDA decisions support the inference that no Altria e-cigarette product could obtain PMTA authorization, but this conclusion rests on a flawed and selective reading of the FDA's press releases. First, Respondents' motion claims the FDA predicated its approval of NJOY Ace on a determination that the product "had 'lower levels of exposure to [harmful and potentially harmful constituent levels ("HPHCs")] compared to' other e-vapor products and to cigarettes." Resps.' Mot. at 7 (quoting Resps.' Ex. C at 1-2). In fact, the FDA press release says that the Ace aerosol had lower levels of HPHCs than cigarette smoke, and that users "**who had used only the authorized NJOY Ace products** had lower levels of exposure to HPHCs compared to the dual users of the **new products** and combustible cigarettes." Resps.' Ex. C at 1 (emphasis added). Thus, the reference to "new products" refers specifically to the NJOY Ace products and *not* to other e-cigarette products.[3] In other words, Respondents incorrectly suggest that the FDA found that NJOY Ace exposed users to fewer

[3] *See* Resps.' Ex. B at 3 (using phrase "new products" in reference to NJOY's newly approved products).

HPHCs than other e-cigarettes when, in fact, the FDA only found that consumers who used only NJOY Ace were exposed to fewer harmful HPHCs than consumers that used the NJOY Ace alongside combustible cigarettes.

Second, Respondents suggest the recent FDA decisions to approve NJOY Ace while denying myBlu turned on the products' ability to convert smokers away from combustible cigarettes. Resps.' Mot. at 4 (citing Resps.' Ex. A at 1-2), 7 (citing Resps.' Ex. C at 1-2). But the FDA press releases do not discuss conversion. Nor do the press releases support Respondents' suggestion that a products' ability to convert adult smokers is the lynchpin of the FDA's PMTA decision-making process. The full paragraphs from the FDA press releases are cited here for context:

> Fontem's myBlu: In reviewing premarket tobacco applications for tobacco products, FDA evaluates the risks and benefits of those tobacco products to the population as a whole, including users and nonusers of the tobacco product, and takes into account, among other things, the likelihood that those who do not currently use tobacco products will start using those tobacco products. Based on the information provided in the applications submitted by Fontem US, LLC for these myblu products and the available evidence, the application lacked sufficient evidence regarding design features, manufacturing, and stability. Additionally, the applications did not demonstrate that the potential benefit to smokers who switch completely or significantly reduce their cigarette use would outweigh the risk to youth. Resps.' Ex. A at 1-2.
>
> NJOY Ace: Additionally, the FDA considered the risks and benefits to the population as a whole, including users and non-users of tobacco products, and importantly, youth. This included review of available data on the likelihood of use of the product by young people. For the authorized products, the FDA determined that the potential benefit to adult smokers who switch completely or significantly reduce their cigarette use, would outweigh the risk to youth, provided that the company follows post-marketing requirements to reduce youth access and youth exposure to their marketing. Resps.' Ex. C at 2.

Indeed, contrary to Respondents' repeated suggestion that the FDA's PMTA determination turns exclusively on conversion potential, the FDA press releases emphasize the importance of the products' potential appeal to youth. The record is clear that while JLI's JUUL product had significant youth appeal, Altria's e-cigarette offerings did not, which increased the likelihood of Altria's products securing PMTA approval. CCFF ¶¶ 1248-53, 1323-52. Thus, the conclusions Respondents ask the Commission to draw are neither supported by the recent FDA decisions nor the record as a whole.

Finally, Respondents' motion implies that to prevail on its claims, Complaint Counsel must show that Altria's existing products would have obtained PMTA approval. This is not the case: but for the JLI Transaction, Altria's existing products could have continued competing for at least several additional years even if those products were never approved by the FDA. This current competition was lost regardless of PMTA approval. Respondents' suggestion that manufacturers only file a PMTA if a product has "a good chance" of being "approved" is belied by the facts. Resps.' Mot. at 4 (citing RX0091). Indeed, Respondents ignore that every other competitor in the closed-system e-cigarette market—even those that had market shares lower than Altria—filed PMTAs for their current products and continue to compete in the closed-system e-cigarette market today. And, as these FDA decisions make clear, many e-vapor products have not received PMTA approval.[4]

[4] Respondents exaggerate the likely impact of MarkTen's formaldehyde issue on its prospects for FDA approval. Indeed, Howard Willard, then-CEO of Altria, was not very concerned about formaldehyde. PX1223. Respondents also fail to mention that Altria had already designed a new battery to solve the formaldehyde issue and that Altria planned to use a data-bridging strategy to include the new battery in its initial MarkTen PMTA. CCFF ¶¶ 1277-78, 1295-96.

CONCLUSION

For the foregoing reasons, Complaint Counsel files this response to Respondents' motion.

Dated: May 24, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 24, 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 notifications of such filing to:

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