PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

COMPLAINT COUNSEL'S THIRD MOTION REQUESTING OFFICIAL NOTICE OF FDA DECISIONS

Pursuant to Commission Rules 3.22 (16 C.F.R. § 3.22), 3.43 (16 C.F.R. § 3.43), and 3.54 (16 C.F.R. § 3.54), Complaint Counsel respectfully requests that the Commission take official notice of (1) the Food and Drug Administration's ("FDA") June 23, 2022 decision denying marketing authorization for all JUUL products sold in the United States ("JUUL Denial"), and (2) the FDA's June 10, 2022 decision granting marketing authorization for two NJOY cigalike devices ("NJOY Authorization"). These FDA decisions are similar to those that have been the subject of previous motions for official notice filed by both Complaint Counsel[1] and Respondents (which

[1] *See* Complaint Counsel's Motion Requesting Official Notice of FDA Decision, March 31, 2022; Complaint Counsel's Second Motion Requesting Official Notice of FDA Decision, May 24, 2022.

Complaint Counsel did not oppose).[2] As the Commission noted, there can be no reasonable dispute about the existence, wide availability, and accuracy of the FDA's decisions.[3] Moreover, like the other FDA decisions for which the parties have sought official notice, these decisions are relevant to Complaint Counsel's claims and Respondents' defenses. Specifically, the JUUL Denial (1) undermines Respondents' pretextual claim that Altria discontinued its e-cigarettes because of regulatory concerns, (2) further illustrates the competitive significance of Altria in the closed-system e-cigarette market, and (3) severely undermines Respondents' claims about the purported procompetitive benefits or efficiencies stemming from Altria's partial acquisition of JUUL Labs, Inc. ("JLI") ("the Transaction"). The NJOY Authorization is material to Complaint Counsel's allegations that, but for the Transaction, Altria would be competing aggressively in the closed-system e-cigarette market today on price, innovation, and other key dimensions of competition. The NJOY Authorization is also material to Respondents' argument that Altria would be unable to secure PMTA approval on its products, including the MarkTen cigalike.

I. FACTS

FDA regulations govern participation in the U.S. e-cigarette industry. In 2016, the FDA issued regulations requiring that manufacturers of new e-cigarette products submit a Premarket Tobacco Application ("PMTA") and obtain a marketing authorization before they can sell their products. Complaint Counsel's Post-Trial Findings of Fact and Conclusions of Law ("CCFF") ¶197. The FDA looks at several factors in making its PMTA determinations, including conversion potential and initiation among non-smokers. CCFF ¶¶1323-27; 1912-17. The FDA

[2] *See* Respondents' Motion for Official Notice of Recent FDA Decisions, May 16, 2022; Complaint Counsel's Response to Respondents' Motion for Official Notice of Recent FDA Decisions, May 24, 2022; Respondents' Motion for Official Notice of myBlu Marketing Denial Letter, June 7, 2022; Complaint Counsel's Response to Respondents' Motion for Official Notice of myBlu Marketing Denial Letter, June 13, 2022.
[3] *See* Order Extending Time for Ruling on Motion for Official Notice of FDA Decision, May 13, 2022.

has explained that "[u]nder the PMTA pathway [], applicants must demonstrate to the agency, among other things, that permitting the marketing of the new tobacco product would be appropriate for the protection of the public health."[4] As part of its evaluation of a PMTA for an e-cigarette product, the FDA "consider[s] the risks and benefits to the population as a whole, including users and non-users of tobacco products, **including youth.**" (emphasis added).[5]

Before its exit, Altria was marketing, developing, and selling multiple e-cigarette products, including the MarkTen cigalike, MarkTen Bold (a cigalike with nicotine salts), and MarkTen Elite (a pod-based e-cigarette). CCFF ¶¶130, 138. JLI has never marketed, developed, or sold a cigalike, and has focused solely on pod-based e-cigarettes. CCFF ¶¶30, 65. Importantly, Altria only pulled its pod-based e-cigarettes because of its purported concern that pod-based products generally contributed to the rise in youth use of e-vapor products; in fact, Altria expressly stated that it did not believe it had an issue with youth access to or use of its pod-based products. CCFF ¶¶812, 987. Altria never cited youth initiation for pulling its cigalike products from the market. *See* CCFF ¶¶989-991. Further, Altria executives were aware that JLI's JUUL product had significant appeal among non-smokers, and among youth in particular. CCFF ¶¶1248-1252.

On June 23, 2022, the FDA issued a press release announcing that the agency had sent marketing denial orders ("MDOs") to JLI for all of its products currently marketed in the United States.[6] The products denied authorization include the JUUL device as well as four types of JUUL pods.[7] According to the FDA's press release, JLI "must stop selling and distributing these products. In addition, those currently on the U.S. market must be removed, or risk enforcement

[4] Exhibit A (FDA, Press Release, *FDA Denies Authorization to Market JUUL Products* (June 23, 2022), https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products) at 3.
[5] Exhibit C (FDA, Press Release, *FDA Issues Marketing Decisions on NJOY Daily E-Cigarette Products* (June 10, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-daily-e-cigarette-products) at 1.
[6] Exhibit A at 1.
[7] *Id*.

action."[8] As FDA Commissioner Dr. Robert M. Califf explained, "[t]he agency has dedicated significant resources to review products from the companies that account for most of the U.S. market. We recognize these make up a significant part of the available products and **many have played a disproportionate role in the rise in youth vaping.**" (emphasis added).[9]

On June 10, 2022, the FDA issued "Marketing Granted Orders" to NJOY LLC ("NJOY") authorizing NJOY to market two disposable e-cigarette products: NJOY Daily Rich Tobacco 4.5% and NJOY Daily Extra Rich Tobacco 6%.[10] Both products are cigalikes. CCFF ¶190. The FDA posted the letter informing NJOY of the approvals to its website[11] and issued a concurrent press release.[12] According to the press release, the FDA concluded that "the potential benefit [of the authorized products] to adult cigarette 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."[13] At the same time, "[t]he FDA also issued marketing denial orders to NJOY for multiple other Daily e-cigarette products."[14]

II. THE COMMISSION SHOULD TAKE OFFICIAL NOTICE OF THE FDA'S DECISIONS

Commission Rule 3.43(f) provides in relevant part that "official notice may be taken of any material fact that is not subject to reasonable dispute in that it is either generally known within

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[8] *Id.*
[9] *Id.* On June 24, 2022, the U.S. Court of Appeals for the D.C. Circuit entered a temporary administrative stay of the MDOs for JLI. Order, *Juul Labs, Inc. v. FDA*, No. 22-1123 (D.C. Cir. June 24, 2022). The court noted the purpose of this administrative stay is to give the court sufficient opportunity to consider JLI's emergency motion for stay pending court review and should not be construed in any way as a ruling on the merits of that motion. *Id.*
[10] Exhibit C at 1.
[11] Exhibit B (FDA, *Premarket Tobacco Product Marketing Granted Orders*, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last visited June 28, 2022)).
[12] Exhibit C.
[13] *Id.* at 1-2.
[14] *Id.* at 1.

the Commission's expertise or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Further, Commission Rule 3.54(a) provides that "[u]pon appeal from or review of an initial decision, the Commission will consider such parts of the record as are cited or as may be necessary to resolve the issues presented *and, in addition, will, to the extent necessary or desirable, exercise all the powers which it could have exercised if it had made the initial decision*." (emphasis added). Thus, the Commission may take official notice of material facts not subject to reasonable dispute even though the evidentiary record is closed.

A. The FDA decisions are appropriate for official notice

The FDA decisions are the public statements of a government agency and widely available on the FDA's website. Under Commission precedent, official notice may be taken of references "generally accepted as reliable." *In re Basic Research*, No. 9318, 2006 WL 271518, at *1 (F.T.C. Jan. 23, 2006). "Matters of official notice include those contained in public records, such as judicial decisions, statutes and regulations, and records and reports of administrative bodies." *In re S.C. State Bd. of Dentistry*, 138 F.T.C. 229, 240 (July 28, 2004); *see also In re Rambus*, No. 9302, 2003 WL 22064718, at *2 (F.T.C. Aug. 27, 2003) (taking judicial notice of the existence of patents and information contained on the face of the patent).

Similarly, federal courts have applied Federal Rule of Evidence 201, the federal rule upon which Commission Rule 3.54 is based,[15] to allow judicial notice (a close analogue to official notice) of government documents available from reliable sources. *See, e.g.*, *Cannon v. District of Columbia*, 717 F.3d 200, 205 n.2 (D.C. Cir. 2013) (taking judicial notice of the contents of a District of Columbia Retirement Board document). Exhibits A, B, and C are public statements

[15] *See, e.g.*, *In re Rambus*, 2003 WL 22064718, at *1-2.

made by the FDA which are readily available on the FDA's official website. The reliability of this information cannot reasonably be called into question.

B. The FDA's JUUL Denial is material to Complaint Counsel's claims and Respondents' defenses

The JUUL Denial both supports Complaint Counsel's claims and undermines Respondents' defenses.[16] First, the FDA's JUUL Denial further undermines Respondents' pretextual assertion that Altria discontinued its e-cigarettes because of a purported concern that its products would not obtain PMTA approval.[17] The evidence is clear that before the Transaction, Altria also had concerns about JUUL's PMTA prospects. CCFF ¶¶1249-53. Indeed, by the summer and fall of 2018, Altria knew that JUUL had a youth-usage issue that could "be very difficult for JUUL in a PMTA context." CCFF ¶1250. The JUUL Denial shows that Altria's concern for JUUL's PMTA prospects were well-founded. It makes no sense that Altria would discontinue its own e-cigarette products, which it admitted had no youth vaping issues, only to purchase a large equity stake in the company sitting in the center of the emerging youth vaping crisis.

Second, the JUUL Denial further illustrates the anticompetitive effect of losing Altria—the third-largest competitor before the Transaction—from the closed-system e-cigarette market. But for the Transaction, Altria would still be competing in that market today. *See, e.g.*, Complaint Counsel's Appeal Brief ("CCAB") at 26; Reply at 11-12. Consumers have already lost the benefit of three and a half years of competition from Altria, both from existing and improved products, and from Altria's individual and joint research and development efforts.[18] CCFF

[16] Regardless of the outcome of JLI's appeal to the D.C. Circuit, the fact that the FDA denied the JUUL PMTA supports Complaint Counsel's case and undermines Respondents' defenses.
[17] Even if Altria believed its existing e-cigarettes might not receive PMTA approval, it made no sense to remove those products *four years* before the then-August 2022 PMTA deadline. *See* Reply Br. to Resps.' Answering Br. ("Reply") at 7-8, 15.
[18] The JUUL Denial illustrates the importance of Altria's strategy to place "a lot of different bets." CCFF ¶1560. Unlike JLI, whose only products are its JUUL device and pods, Altria was pursuing multiple paths to compete in closed-system e-cigarettes with different products. Those paths included its existing MarkTen cigalikes and

¶¶1408-730. With the removal of JLI, one of the few remaining large e-cigarette competitors, an already highly concentrated market will become even more concentrated. The harm stemming from the loss of competition from Altria—who as the largest tobacco company in the U.S. was particularly well positioned to compete[19]—will only become more pronounced.

Third, the JUUL Denial effectively eliminates Respondents' *only* remaining claim of efficiencies or procompetitive benefit stemming from the Transaction: Altria's provision of regulatory services to assist JLI in obtaining PMTA authorization for JUUL. *See* Respondents' Answering Brief at 39-40; CCAB at 39 n.35. As described in Complaint Counsel's briefs, this purported efficiency is fatally flawed regardless of the outcome of JUUL's PMTA, as it is not verifiable, not merger specific, and results from an anticompetitive reduction in output or service. Reply at 18; *see also* CCAB at 41-43 (discussing why the regulatory services justification also fails under a Section 1 framework); Reply at 16-17 (same). But the FDA's denial of the JUUL PMTA removes all doubt as to whether the Transaction resulted in any efficiencies or procompetitive benefits. It did not.

C. The FDA's NJOY Authorization is material to Complaint Counsel's claims and Respondents' defenses

The FDA's authorization of two NJOY Daily products is also material to Complaint Counsel's claims and Respondents' defenses. Like Altria's discontinued MarkTen cigalike products, the newly approved NJOY products are cigalikes rather than pod-based products. *See* Complaint Counsel's Reply Findings of Fact ¶¶262-63, 1332; CCFF ¶190. In its Initial Decision, the Court found that Altria's e-cigarette products were not competitively significant based

MarkTen Elite pod-based products (including improvements like the new battery for MarkTen and the new gasket for Elite), a new version of Elite (Elite 2.0), its R&D collaboration with PMI, the planned commercialization of PMI's pod-based VEEV e-cigarette, and a variety of other ongoing R&D projects. CCFF ¶¶1408-730.

[19] CCAB at 3-4; CCFF ¶¶493-522.

largely on its conclusion that Altria's products lacked conversion potential and, as such, would be unlikely to receive PMTA approval. Initial Decision ("ID") 96-97. In reaching this conclusion, the Court credited testimony from Altria executives that the cigalike format would not appeal to a sufficiently broad and deep pool of smokers to generate sufficient conversion potential (Initial Decision Finding ("IDF") 291), and further cited Respondents' claim that the MarkTen cigalikes' lack of conversion potential raised serious doubts for receiving FDA approval (ID27). But the FDA's decision to grant marketing authorization for two NJOY cigalikes—as well as its prior decisions to grant marketing authorization for the Vuse Solo cigalike, the Vuse Vibe cigalike, the Vuse Ciro cigalike, and the Logic Power cigalike[20]—severely undercuts Respondents' claims that certain of Altria's existing products would be unable to obtain FDA approval due to their cigalike form. The NJOY Authorization shows that conversion is only one of the factors the FDA considers in evaluating PMTAs, and that cigalikes can in fact secure PMTA approval.

* * * * *

The Commission should consider the FDA's most recent actions with respect to PMTAs for e-cigarettes when it evaluates Complaint Counsel's claims and Respondents' defenses. In light of the importance of the PMTA process to the claims and defenses at issue in this case, the agency's recent denial of JUUL's PMTA and authorization of the two NJOY cigalikes satisfy the standard for materiality under Rule 3.43(f). Based on the reliability of this information and its materiality, the JUUL Denial and NJOY Authorization are appropriate for official notice by the Commission.

[20] *See* IDF 261; Complaint Counsel's Motion Requesting Official Notice of FDA Decision, March 31, 2022; Complaint Counsel's Second Motion Requesting Official Notice of FDA Decision, May 24, 2022.

CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully requests that the Commission grant its Third Motion Requesting Official Notice of FDA Decisions.

Dated: July 5, 2022

Respectfully submitted,

s/ Meredith Levert

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Upon consideration of Complaint Counsel's Third Motion Requesting Official Notice of FDA Decisions, it is hereby ORDERED that the motion is GRANTED.

By the Commission.

April Tabor
Secretary

ISSUED:

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In a conversation over the course of July 1, 2022, Complaint Counsel Stephen Rodger and James Abell and Respondents' counsel Jonathan Moses conferred in a good faith effort to resolve by agreement the issues raised by the attached motion and were unable to reach an agreement.

Dated: July 5, 2022

By: *s/ James Abell*
James Abell

Counsel Supporting the Complaint

EXHIBIT A

FDA NEWS RELEASE

FDA Denies Authorization to Market JUUL Products

Currently Marketed JUUL Products Must Be Removed from the US Market

For Immediate Release:

June 23, 2022

On June 24, 2022, the U.S. Court of Appeals for the D.C. Circuit entered a temporary administrative stay of the marketing denial order for Juul Labs Inc. The court notes the purpose of this administrative stay is to give the court sufficient opportunity to consider petitioner's forthcoming emergency motion for stay pending court review and should not be construed in any way as a ruling on the merits of that motion.

Español (/news-events/press-announcements/la-fda-niega-la-autorizacion-para-comercializar-los-productos-juul)

Today, the U.S. Food and Drug Administration issued marketing denial orders (MDOs) (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial) to JUUL Labs Inc. for all of their products currently marketed in the United States. As a result, the company must stop selling and distributing these products. In addition, those currently on the U.S. market must be removed, or risk enforcement action. The products include the JUUL device and four types of JUULpods: Virginia tobacco flavored pods at nicotine concentrations of 5.0% and 3.0% and menthol flavored pods at nicotine concentrations of 5.0% and 3.0%. Retailers should contact JUUL with any questions about products in their inventory.

"Today's action is further progress on the FDA's commitment to ensuring that all e-cigarette and electronic nicotine delivery system products currently being marketed to consumers meet our public health standards," said FDA Commissioner Robert M. Califf, M.D. "The agency has dedicated significant resources to review products from the companies that account for most of the U.S. market. We recognize these make up a significant part of the available products and many have played a disproportionate role in the rise in youth vaping."

These MDOs only pertain to the commercial distribution, importation and retail sales of these products, and do not restrict individual consumer possession or use—the FDA cannot and will not enforce against individual consumer possession or use of JUUL products or any other tobacco products.

After reviewing the company's premarket tobacco product applications (PMTAs) (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications), the FDA determined that the applications lacked sufficient evidence regarding the toxicological profile of the products to demonstrate that marketing of the products would be appropriate for the protection of the public health. In particular, some of the company's study findings raised concerns due to insufficient and conflicting data – including regarding genotoxicity and potentially harmful chemicals leaching from the company's proprietary e-liquid pods – that have not been adequately addressed and precluded the FDA from completing a full toxicological risk assessment of the products named in the company's applications.

To date, the FDA has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods. However, the MDOs issued today reflect FDA's determination that there is insufficient evidence to assess the potential toxicological risks of using the JUUL products. There is also no way to know the potential harms from using other authorized or unauthorized third-party e-liquid pods with the JUUL device or using JUULpods with a non-JUUL device. The FDA recommends against modifying or adding substances to tobacco products. JUUL users are encouraged to report any unexpected health problems or product problems to the FDA through the Safety Reporting Portal (https://safetyreporting.hhs.gov/) and to seek medical attention as necessary.

"The FDA is tasked with ensuring that tobacco products sold in this country meet the standard set by the law, but the responsibility to demonstrate that a product meets those standards ultimately falls on the shoulders of the company," said Michele Mital, acting director of the FDA's Center for Tobacco Products. "As with all manufacturers, JUUL had the opportunity to provide evidence demonstrating that the marketing of their products meets these standards. However, the company did not provide that evidence and instead left us with significant questions. Without the data needed to determine relevant health risks, the FDA is issuing these marketing denial orders."

Any products subject to an MDO may not be offered for sale or distributed in the United States, or the FDA may take enforcement action.

In addition to ensuring that JUUL complies with this order, as with unauthorized products generally, the FDA intends to ensure compliance by distributors and retailers. Specifically, the FDA notes that all new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action.

As the FDA has stated in the past, unauthorized electronic nicotine delivery system (ENDS) products for which no application is pending, including for example, those with an MDO, are among our highest enforcement priorities. Therefore, the FDA encourages retailers to discuss

products in their inventory with their suppliers including the current status of any particular tobacco product's marketing application or marketing authorization. Manufacturers will be the best source of that information and retailers should rely on manufacturers directly to inform decisions about which products to continue selling.

There are many resources (https://www.fda.gov/tobacco-products/health-effects-tobacco-use/quitting-smoking-and-other-tobacco-public-health-resources) to help smokers who want to quit. Quitting all tobacco products is the best possible path to good health. Some current JUUL users who will not have access to JUUL products following this action or current smokers who want to transition away from cigarettes and cigars may decide to switch to other ENDS products (https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) that have been reviewed and authorized by the FDA based on their potential to benefit adult smokers.

To date, the FDA has authorized 23 ENDS products. Under the PMTA pathway (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications), applicants must demonstrate to the agency, among other things, that permitting the marketing of the new tobacco product would be appropriate for the protection of the public health.

The FDA continues to work to complete its review of the remaining pending applications for deemed products submitted by the Sept. 9, 2020, deadline.

Related Information

- Tobacco Products Marketing Orders (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Premarket%20Tobacco%20Product%20Applications%20(PMTA))
- Premarket Tobacco Product Applications (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications)
- Quitting Smoking and Other Tobacco Public Health Resources (https://www.fda.gov/tobacco-products/health-effects-tobacco-use/quitting-smoking-and-other-tobacco-public-health-resources)
- Safety Reporting Portal for Tobacco Products (https://www.fda.gov/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Inquiries

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More Press Announcements (/news-events/newsroom/press-announcements)

EXHIBIT B

Premarket Tobacco Product Marketing Granted Orders

2022 Premarket Tobacco Product Marketing Granted Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary
NJOY LLC	NJOY DAILY Rich Tobacco 4.5% (/media/159137/download)	ENDS	06/10/2022	PM0000630 (/media/159136/download) [Executive Summary]
NJOY LLC	NJOY DAILY EXTRA Rich Tobacco 6% (/media/159137/download)	ENDS	06/10/2022	PM0000631 (/media/159136/download) [Executive Summary]
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (/media/158373/download)	ENDS	05/12/2022	PM0000635 (/media/158374/download) [Executive Summary]
R.J. Reynolds Vapor Company	Vuse Vibe Tank Original 3.0% (/media/158373/download)	ENDS	05/12/2022	PM0000636 (/media/158374/download) [Executive Summary]
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (/media/158373/download)	ENDS	05/12/2022	PM0004287 (/media/158374/download) [Executive Summary]
R.J. Reynolds Vapor Company	Vuse Ciro Power Unit (/media/158373/download)	ENDS	05/12/2022	PM0000646 (/media/158374/download) [Executive Summary]
R.J. Reynolds Vapor Company	Vuse Ciro Cartridge Original 1.5% (/media/158373/download)	ENDS	05/12/2022	PM0000712 (/media/158374/download) [Executive Summary]
R.J. Reynolds Vapor Company	Vuse Ciro Power Unit (/media/158373/download)	ENDS	05/12/2022	PM0004293 (/media/158374/download) [Executive Summary]
NJOY LLC	NJOY ACE Device (/media/157958/download)	ENDS	04/26/2022	PM0000613 (/media/157959/download) [Executive Summary]
NJOY LLC	NJOY ACE POD Classic Tobacco 2.4% (/media/157958/download)	ENDS	04/26/2022	PM0000614 (/media/157959/download) [Executive Summary]
NJOY LLC	NJOY ACE POD Classic Tobacco 5% (/media/157958/download)	ENDS	04/26/2022	PM0000615 (/media/157959/download) [Executive Summary]
NJOY LLC	NJOY ACE POD Rich Tobacco 5% (/media/157958/download)	ENDS	04/26/2022	PM0000622 (/media/157959/download) [Executive Summary]
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package (/media/158752/download)	ENDS	03/24/2022	PM0000529 (/media/158754/download)
Logic Technology Development LLC	Logic Vapeleaf Cartridge/Capsule Package (/media/158752/download)	ENDS	03/24/2022	PM0000530 (/media/158754/download)
Logic Technology Development LLC	Logic Vapeleaf Tobacco Vapor System (/media/158752/download)	ENDS	03/24/2022	PM0000531 (/media/158754/download)

Logic Technology Development LLC	Logic Pro Tobacco e-Liquid Package (/media/158752/download)	ENDS	03/24/2022	PM0000535 (/media/158754/download)
Logic Technology Development LLC	Logic Pro Capsule Tank System (/media/158752/download)	ENDS	03/24/2022	PM0000536 (/media/158754/download)
Logic Technology Development LLC	Logic Pro Capsule Tank System (/media/158752/download)	ENDS	03/24/2022	PM0000537 (/media/158754/download)
Logic Technology Development LLC	Logic Power Tobacco e-Liquid Package (/media/158752/download)	ENDS	03/24/2022	PM0000540 (/media/158754/download)
Logic Technology Development LLC	Logic Power Rechargeable Kit (/media/158752/download)	ENDS	03/24/2022	PM0000541 (/media/158754/download)

Temporary Compliance Waiver
The linked files may not be fully accessible to readers using assistive technology. We regret any inconvenience that this may cause. In the event you are unable to read these documents or portions thereof, please email AskCTP@fda.hhs.gov (mailto:AskCTP@fda.hhs.gov) or call 1-877-287-1373.

Before making documents available to the public, FDA must redact trade secret and confidential commercial information (CCI) and ensure documents posted to the FDA website are accessible to everyone. For these reasons, the full decision summary for marketing authorizations may not be posted to the website until after the order issuance date. In the interim, to provide as much information as possible at the time of order issuance, we are making redacted versions of the order letter and the "Executive Summary" section of the decision summary available to broadly explain the public health rationale for authorization of these products.

2021 Premarket Tobacco Product Marketing Granted Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary
U.S. Smokeless Tobacco Company LLC	VERVE® Discs Blue Mint (/media/153254/download)	Other	10/19/2021	PM0000470 (/media/153255/download)
U.S. Smokeless Tobacco Company LLC	VERVE® Chews Blue Mint (/media/153254/download)	Other	10/19/2021	PM0000471 (/media/153255/download)
U.S. Smokeless Tobacco Company LLC	VERVE® Discs Green Mint (/media/153254/download)	Other	10/19/2021	PM0000472 (/media/153255/download)
U.S. Smokeless Tobacco Company LLC	VERVE® Chews Green Mint (/media/153254/download)	Other	10/19/2021	PM0000473 (/media/153255/download)
R.J. Reynolds Vapor Company	Vuse Solo Power Unit (/media/153010/download)	ENDS	10/12/2021	PM0000551 (/media/153017/download)
R.J. Reynolds Vapor Company	Vuse Replacement Cartridge Original 4.8% G1 (/media/153010/download)	ENDS	10/12/2021	PM0000553 (/media/153017/download)
R.J. Reynolds Vapor Company	Vuse Replacement Cartridge Original 4.8% G2 (/media/153010/download)	ENDS	10/12/2021	PM0000560 (/media/153017/download)

To prioritize resources and provide the public with the most helpful information in a timely manner, starting FY 2021 FDA will be posting only order letters and decision summaries related to marketing orders on the FDA website. However, other documents, such as the environmental assessment (EA) and finding of no significant impact (FONSI), will remain available to the public upon request. To request records related to a recently issued marketing order please submit a FOIA request (/regulatory-information/freedom-information/how-make-foia-request). For general tobacco-related questions and information please contact CTP (/tobacco-products/about-center-tobacco-products-ctp/contact-ctp).

2020 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)
Philip Morris Products S.A..	IQOS System Holder and Charger (/media/144700/download)	Cigarettes*	12/7/2020	PM0000634 (/media/144701/download)	EA0000634 (/media/144698/download)	FONSI0000634 (/media/144699/download)

*Noncombusted cigarettes

2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)
22nd Century Group Inc.	Moonlight ® Menthol (/media/133635/download)	Cigarettes	12/17/2019	PM0000492 (/media/133633/download)	EA0000492 (/media/133634/download)	FONSI0000492 (/media/133623/download)
22nd Century Group Inc.	Moonlight ® (/media/133635/download)	Cigarettes	12/17/2019	PM0000491 (/media/133633/download)	EA0000491 (/media/133634/download)	FONSI0000491 (/media/133623/download)
Philip Morris Products S.A.	Marlboro Heatsticks (/media/124248/download)	Cigarettes*	4/30/2019	PM0000424 (/media/124247/download)	EA0000424 (/media/134458/download)	FONSI0000424 (/media/134457/download)
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks (/media/124248/download)	Cigarettes*	4/30/2019	PM0000425 (/media/124247/download)	EA0000425 (/media/134458/download)	FONSI0000425 (/media/134457/download)
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks (/media/124248/download)	Cigarettes*	4/30/2019	PM0000426 (/media/124247/download)	EA0000426 (/media/134458/download)	FONSI0000426 (/media/134457/download)
Philip Morris Products S.A.	IQOS System Holder and Charger (/media/124248/download)	Cigarettes*	4/30/2019	PM0000479 (/media/124247/download)	EA0000479 (/media/134458/download)	FONSI0000479 (/media/134457/download)

*Noncombusted cigarettes

2015 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	D
Swedish Match North America, Inc.	General Loose (/media/94616/download)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Dry Mint Portion Original Mini (http://wayback.archive-it.org/7993/20180425120157/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472133.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Portion Original Large (http://wayback.archive-it.org/7993/20180425120157/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472134.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Classic Blend Portion White Large - 12ct (http://wayback.archive-it.org/7993/20180425120157/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472137.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Mint Portion White Large (http://wayback.archive-it.org/7993/20180425120157/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472138.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Nordic Mint Portion White Large - 12ct (http://wayback.archive-it.org/7993/20180425120157/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472140.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Portion White Large (http://wayback.archive-it.org/7993/20180425120157/https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472141.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	Smokeless Tobacco	11/10/2015	F (
Swedish Match North America, Inc.	General Wintergreen Portion White Large (/media/94633/download)	Smokeless Tobacco	11/10/2015	F (

Additional Resources

- FDA permits sale of two new reduced nicotine cigarettes through premarket tobacco product application pathway (/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application)

- FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway (/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway)
- Premarket Tobacco Product Applications (/tobacco-products/review-evaluation-process/tobacco-product-marketing-orders)
- Guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) (/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends)
- Draft Guidance for Industry Applications for Premarket Review of New Tobacco Products (/tobacco-products/rules-regulations-guidance/applications-premarket-review-new-tobacco-products)

EXHIBIT C

FDA Issues Marketing Decisions on NJOY Daily E-Cigarette Products

On June 10, the FDA issued decisions on multiple NJOY Daily e-cigarette products, including the authorization of two new tobacco products through the Premarket Tobacco Product Application (PMTA) pathway. The FDA issued marketing granted orders (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) to NJOY LLC for its tobacco-flavored Daily disposable e-cigarettes – NJOY Daily Rich Tobacco 4.5% and NJOY Daily Extra Rich Tobacco 6%.

This authorization allows these products to be legally marketed in the U.S. While this action permits these specific products to be sold in the U.S., it does not mean these products are safe nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.

The FDA also issued marketing denial orders to NJOY for multiple other Daily e-cigarette products. Any of those products that remain on the market must be removed, or FDA may take enforcement action. Retailers should contact NJOY with any questions about products in their inventory. Applications for two menthol-flavored Daily products remain under FDA review.

Under the PMTA pathway, the applicant must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. The authorized NJOY products were found to meet this standard because, among several key considerations, the overall toxicological risk to the users of the new products is lower compared to combusted cigarette smoke due to significant reductions in aerosol harmful and potentially harmful constituents (HPHCs) from the new products compared to cigarettes. Additionally, estimates of complete switching from cigarettes to the new products for current adult smokers was at a level higher than what is typically seen in the literature for estimates of complete switching to electronic nicotine delivery systems (ENDS). Therefore, the applicant has demonstrated that some current adult smokers are interested in the new products to assist in decreasing or quitting their cigarette use, and these products have the potential to benefit that group.

Importantly, the FDA considered the risks and benefits to the population as a whole, including users and non-users of tobacco products, including 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 cigarette 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.

As shown in the 2021 National Youth Tobacco Survey (NYTS) (/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic), among youth who currently used e-cigarettes, the most commonly used e-cigarette device type was disposables. The agency takes these data very seriously and strongly considered risks to youth when reviewing the applications for these products. Although the NYTS showed the relative popularity of disposable ENDS among youth, it also indicated that the most commonly used flavor types among youth who currently used any type of e-cigarettes were flavors such as fruit, candy or mint, and not tobacco flavors. These data informed the FDA's decision to authorize the tobacco-flavored products because these products are less appealing to youth and authorizing these products may be beneficial for current adult smokers who completely switch to ENDS or significantly reduce their cigarette consumption.

Moreover, this authorization imposes strict marketing restrictions on the company to greatly reduce the potential for youth exposure to tobacco advertising for these products. The FDA will closely monitor how these products are marketed and will act as necessary if the company fails to comply with any applicable statutory or regulatory requirements, or if there is a notable increase in the number of non-smokers—including youth—using these products.

The FDA may suspend or withdraw a marketing granted order issued under the PMTA pathway for a variety of reasons if the agency determines the continued marketing of a product is no longer "appropriate for the protection of the public health," such as if there is a notable increase in youth initiation.

Before making marketing granted order decision documents available to the public, the FDA must redact trade secret and confidential commercial information (CCI) and ensure documents posted to the FDA website are accessible to everyone. For these reasons, the full decision summary for marketing authorizations may not be posted to the Premarket Tobacco Product Marketing Granted Orders webpage (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) until after the order issuance date. In the interim, to provide as much information as possible at the time of order issuance, the FDA is making redacted versions of the marketing granted order letter and the "Executive Summary" section of the decision summary available to broadly explain the public health rationale for authorization of these products.

CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2022, I served the foregoing document via email to:

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I also certify that I delivered via electronic mail a copy of the foregoing document to:

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