UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. 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**

ORDER GRANTING IN PART COMPLAINT COUNSEL'S THIRD MOTION FOR OFFICIAL NOTICE

On July 5, 2022, Complaint Counsel moved for the Commission to take official notice of (1) the Food and Drug Administration's June 23, 2022 decision denying marketing authorization (known as "PMTA Approval") for all JUUL Labs, Inc. ("JLI") products sold in the United States ("JLI Decision") and (2) the FDA's June 10, 2022 decision granting marketing authorization for two NJOY e-vapor devices ("NJOY Decision"). Complaint Counsel's Third Motion Requesting Official Notice of FDA Decisions ("Third Motion"). On July 15, 2022, Respondents filed a Response to rebut Complaint Counsel's characterizations of the FDA's decisions and their significance. Respondents, however, state that they do not oppose taking official notice of the JLI Decision. Respondents' Response to Complaint Counsel's Third Motion Requesting Official Notice of FDA Decisions at 2 ("Response"). While Respondents argue that the NJOY Decision has no bearing on the commercial and regulatory prospects of Altria's products, Respondents do not state opposition to official notice of the NJOY Decision. *Id*. at 7-8.

Commission Rule 3.43(f), 16 C.F.R. § 3.43(f), authorizes the Commission to take "official notice" of any material fact that is not subject to reasonable dispute in that it is either generally known within the Commission's expertise, or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. A material fact is one "that might affect the outcome of the suit under the governing law[.]" *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986).

We find that the FDA's JLI and NJOY Decisions are not subject to reasonable dispute in that they are capable of accurate and ready determination by resort to sources whose accuracy

cannot reasonably be questioned, as required by Rule 3.43(f). Under our precedent, official notice may be taken of references "generally accepted as reliable." *In re Basic Research, LLC,* 2006 WL 271518, at *1 (F.T.C. Jan. 23, 2006) (citing *In re Thompson Medical Co.,* 104 F.T.C. 648, 790 (1984)). "Matters of official notice include those contained in public records, such as judicial decisions, statutes, regulations, and 'records and reports of administrative bodies.'" *In re S.C. State Bd. of Dentistry,* 138 F.T.C. 229, 240 (2004) (citing *United States v. Ritchie,* 342 F.3d 903, 909 (9th Cir. 2003)). The fact of the JLI and NJOY Decisions, as reported in FDA documents, is not subject to reasonable dispute. *See* Order Extending Time for Ruling on Motions for Official Notice of FDA Decisions and FDA Marketing Denial Letter at 3 (July 7, 2022); Order Extending Time for Ruling on Motion for Official Notice of FDA Decision at 2 (May 13, 2022).

Commission Rule 3.43(f) also requires that a fact be material for us to take official notice of it. Our materiality analysis differs for the JLI and NJOY Decisions. Complaint Counsel explain that the JLI Decision denied marketing authorization for all JLI products currently marketed in the United States. Its terms bar JLI from selling and distributing its products. Third Motion at 3. A follow-on FDA order, issued July 5, 2022 (the "July 5 FDA Order"), however, has stayed the effect of the JLI Decision pending further FDA review. Response at Exhibit A to Exh. B.[1] The parties agree that JLI is a major competitor in the e-cigarette industry, and a prohibition on its continued sales activities would be among the facts considered in our assessment of the competitive landscape following the transaction challenged in this proceeding. Consequently, we find the JLI Decision to be material within the meaning of Rule 3.43(f). Given that we also have found that the JLI Decision is not subject to reasonable dispute, it is properly subject to official notice. Under the same reasoning, we also find it appropriate to take official notice of the July 5 FDA Order.

We are unable to assess the materiality of the NJOY Decision at this time. Unlike the JLI Decision, which pertains to the marketability of the products of one of the combining parties in this proceeding, the NJOY Decision involves the e-vapor products of a third party. Complaint Counsel explain that the NJOY Decision granted marketing authorization to NJOY LLC for two disposable NJOY Daily cigalike products. Third Motion at 4, 7. According to Complaint Counsel, the FDA's approval of the NJOY products tends to refute Respondents' claims that certain of Altria's products would have been unlikely to receive PMTA approval due to their cigalike form and their lack of conversion potential. *Id.* at 8. By showing that conversion is only one of the factors the FDA considers and that cigalikes can in fact win PMTA approval, Complaint Counsel argue, the NJOY Decision undermines the ALJ's conclusion that Altria's products were not competitively significant. *Id.* at 7-8. According to Respondents, however, NJOY Daily is "very different" from Altria's MarkTen cigalike and operates in a market segment where neither Altria nor JLI has ever had a presence. Response at 7. Respondents thus deny that the NJOY Decision has any bearing on the commercial and regulatory prospects of Altria's products. *Id*.

Whether the NJOY Decision is material depends in part on what it implies about the PMTA approval process and the PMTA approval prospects for Altria's former cigalike products.

[1] *See* Response at 1-2. JLI has petitioned for review of the FDA's denial; judicial review is being held in abeyance while FDA's review is in progress. *Id*. at 2 n.1; *see also id*. at Exh. D.

These issues, the materiality assessment, and the official notice determination of which materiality is a part, will benefit from thorough analysis of the briefing and from the forthcoming oral argument in connection with Complaint Counsel's appeal. Pursuant to Commission Rule 3.22(a),[2] we find that these factors constitute good cause to extend until issuance of a final opinion and order in this matter the time for ruling on the portion of the Third Motion directed to the NJOY Decision.

Accordingly,

IT IS HEREBY ORDERED THAT Complaint Counsel's Third Motion Requesting Official Notice of FDA Decisions, filed on July 5, 2022, is **GRANTED IN PART**;

IT IS FURTHER ORDERED THAT the Commission hereby takes official notice of the Food and Drug Administration's June 23, 2022 decision denying marketing authorization for all JUUL Labs, Inc. products sold in the United States and the July 5 FDA Order staying the effect of the aforementioned June 23 decision pending further FDA review; and

IT IS FURTHER ORDERED THAT the deadline for ruling on Complaint Counsel's motion to take official notice of the FDA's June 10, 2022 decision granting marketing authorization for certain NJOY e-vapor devices is extended until the issuance of the Commission's final opinion and order in this matter.

By the Commission.

April J. Tabor
Secretary

SEAL:
ISSUED: August 24, 2022

[2] Under Commission Rule 3.22(a), 16 C.F.R. § 3.22(a), the Commission must rule on the Third Motion "within 45 days of the filing of the last-filed answer to the motion, if any, unless the Commission determines there is good cause to extend the deadline."