UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued Sept. 23, 2020 Decided Dec. 1, 2020

No. 20-5048

MOOSE JOOCE, ET AL.,
APPELLANTS

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Consolidated with 20-5049, 20-5050

Appeals from the United States District Court
for the District of Columbia
(No. 1:18-cv-00203)
(No. 1:18-cv-01615)
(No. 1:19-cv-00372)

Jonathan Wood argued the cause for appellants. With him on the briefs were *Damien M. Schiff* and *Oliver Dunford*.

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Mark B. Stern* and *Joshua Revesz*, Attorneys, *Robert P. Charrow*, General Counsel, U.S. Department of Health and Human Services, and *Peter G. Dickos*, Associate Chief Counsel, Food and Drug Administration.

Before: ROGERS and PILLARD, *Circuit Judges*, and SENTELLE, *Senior Circuit Judge*.

Opinion of the Court by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: Less than a year ago, the court rejected three challenges by an e-cigarette manufacturer and distributor, and an e-cigarette industry group to a rule deeming e-cigarettes to be "tobacco products" subject to regulation under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("the Act"). In *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271 (D.C. Cir. 2019), the court held that it was "entirely rational and nonarbitrary [for the Food and Drug Administration ("FDA")] to apply to e-cigarettes the Act's baseline requirement that, before *any* new tobacco product may be marketed, its manufacturer show the FDA that selling it is consistent with the public health." The court also rejected First Amendment objections to the Act's barring of claims that e-cigarettes are safer than existing products absent such a demonstration and ban on the distribution of free e-cigarette samples. *Id.* at 272. Now other e-cigarette manufacturers and retailers, and a nonprofit organization focused on tobacco harm reduction raise two constitutional challenges to the rule. Under this court's precedents, their Appointments Clause challenge lacks merit and their First Amendment challenge is foreclosed. Accordingly, we affirm the grant of summary judgment to the FDA.

I.

The Act authorizes the Secretary of the Department of Health and Human Services to regulate the manufacture, sale, and distribution of

tobacco products. It permits the Secretary to deem products to be "tobacco products" subject to the Act's requirements. 21 U.S.C. § 387a(b) (2018). One such requirement is the preclearance pathway for manufacturers seeking to market a "modified risk tobacco product," defined as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 387k(b)(1). Under the Act, a modified risk tobacco product may be commercially marketed only if the Secretary determines that the manufacturer has demonstrated that the product, as actually used by consumers, meets two requirements. *Id.* § 387k(g)(1). First, the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users." *Id.* § 387k(g)(1)(A). Second, it will "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.* § 387k(g)(1)(B).

The Secretary of the Department delegated rulemaking authority to the FDA Commissioner. *See, e.g.*, FDA Staff Manual Guide § 1410.10 (Aug. 26, 2016); *id.* § 1410.10 (Nov. 17, 2015). The FDA Commissioner, in turn, redelegated rulemaking authority to the FDA Associate Commissioner for Policy. *See id.* § 1410.21(1)(G) (July 5, 2012). According to the 2012 FDA Staff Manual Guide, the Associate Commissioner for Policy had the authority to "perform any of the functions of the Commissioner with respect to the issuance of [Federal Register] notices and proposed and final regulations of the Food and Drug Administration." *Id.*

In April 2014, the FDA published a proposed rule to deem e-cigarettes, among other items, "tobacco products" under the Act. *See* 79 Fed. Reg. 23,142, 23,143 (Apr. 25, 2014). The comment period was extended until August 8, 2014. *See id.* at 35,711 (June 24, 2014). After considering comments, FDA Associate Commissioner for Policy Leslie Kux promulgated a rule in May 2016 that deemed e-cigarettes to be "tobacco products" subject to the Act's requirements. *See* Deeming Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,974, 28,976 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143) ("Deeming Rule").

On January 30, 2018, appellants sued the FDA challenging the Deeming Rule under the Appointments Clause and the First Amendment of the Constitution. The district court, exercising its discretion to consider the Appointments Clause challenge even though it was not raised during the rulemaking, granted summary judgment to the FDA. Appellants appeal, and our review is *de novo*, *see Mayo v. Reynolds*, 875 F.3d 11, 19 (D.C. Cir. 2017).

II.

The Appointments Clause requires that "all . . . Officers of the United States" be appointed by the President "by and with the Advice and Consent of the Senate." U.S. CONST. art. II, § 2, cl. 2. "This requirement is the 'default manner of appointment,' *Edmond v. United States*, 520 U.S. 651, 660, 117 S. Ct. 1573, 137 L.Ed.2d 917 (1997), with the only exception being that Congress may vest the appointment of 'inferior Officers' in 'the President alone,' 'Courts of

Law,' and 'the Heads of Departments,' U.S. CONST. art. II, § 2, cl. 2." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 11 (D.C. Cir. 2019).

Appellants contend that the position of Associate Commissioner for Policy may be filled by only a properly appointed officer of the United States, and that Kux was not appointed as either an inferior or principal officer. They maintain that Kux's issuance of the Deeming Rule was consequently in violation of the Appointments Clause and void *ab initio*. *See* Appellants' Br. 49–60. The FDA rejects the challenge to Kux's authority and points further to ratifications of the Deeming Rule by FDA Commissioners Robert Califf and Scott Gottlieb. Either ratification, it maintains, suffices to render the Rule constitutional. *See* Appellees' Br. 16–27, 31–38.

"Ratification occurs when a principal sanctions the prior actions of its purported agent." *Doolin Sec. Sav. Bank, F.S.B. v. Office of Thrift Supervision*, 139 F.3d 203, 212 (D.C. Cir. 1998) (citing RESTATEMENT (SECOND) OF AGENCY § 82 (1958)), *superseded by statute on other grounds*, Federal Vacancies Reform Act of 1998, Pub. L. No. 105-277, 112 Stat. 2681 (1998) (codified at 5 U.S.C. §§ 3345 to 3349d), as this court recognized in *Guedes*, 920 F.3d at 13. This court has repeatedly recognized that ratification can remedy a defect arising from the decision of an improperly appointed official, such as the alleged defect arising from the issuance of the Deeming Rule by Associate Commissioner for Policy Kux. *Wilkes-Barre Hosp. Co., LLC v. NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017) (citing *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 796 F.3d 111, 117–21, 124 (D.C. Cir. 2015)). Even assuming for purposes of argument, as

appellants object, that Kux's issuance of the Deeming Rule violated the Appointments Clause and that Commissioner Califf's general ratification of prior actions by the FDA as part of an agency reorganization was invalid, Commissioner Gottlieb's ratification cured any Appointments Clause defect.

A.

On April 3, 2019, noting that the "authority under which the Deeming Rule was issued has been questioned in litigation," then-FDA Commissioner Scott Gottlieb stated: "To resolve these questions, I hereby affirm and ratify the Deeming Rule as of the date it was published in the Federal Register on May 10, 2016, including all regulatory analysis certifications contained therein." Ratification of the Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (signed by Scott Gottlieb, M.D., on Apr. 3, 2019). He specified: "I undertake this action based on my careful review of the rule, my knowledge of its provisions, and my close involvement in policy matters relating to this rule and its implementation, as well as its public health importance." *Id.*

Appellants' challenges to the effectiveness of Commissioner Gottlieb's ratification fail. They maintain that Commissioner Gottlieb lacked the authority to ratify the Deeming Rule after they filed suit in federal district court. Even assuming this challenge is not forfeited by their failure to raise it in the district court, *see Salazar ex rel. Salazar v. District of Columbia*, 602 F.3d 431, 437 (D.C. Cir. 2010), appellants fail to distinguish *FEC v. Legi-Tech, Inc.*, 75 F.3d 704, 707–09 (D.C. Cir. 1996), where the court held that the Federal Election Commission effectively ratified its prior actions even though its ratification

occurred after Legi-Tech alleged an Appointments Clause violation.

Appellants further maintain that "Commissioner Gottlieb lacked the power to issue the Deeming Rule in April 2019 because to do so would have been arbitrary and capricious." Appellants' Br. 28. In appellants' view, for ratification to be effective, a ratifying party "should be able not merely to do the act ratified at the time the act was done, *but also at the time the ratification was made*." *Id.* (quoting *FEC v. NRA Political Victory Fund*, 513 U.S. 88, 98 (1994)). Relying on *Butte County v. Hogen*, 613 F.3d 190 (D.C. Cir. 2010), for the proposition that administrative officials must consider new evidence in order to make non-arbitrary, reasoned decisions, appellants note that during the nearly three years between the Deeming Rule's issuance and Commissioner Gottlieb's ratification, "dozens of public comments submitted to FDA had pointed the Commissioner to a wealth of new evidence regarding the benefits of vaping to public health." Appellants' Br. 30. *Butte County* does not advance appellants' position. In that case, the agency failed to consider a report that was submitted while the "issue was still pending before the Secretary." *Butte County*, 613 F.3d at 195. Here, the rulemaking record closed in 2016 and consequently Commissioner Gottlieb had no such obligation to consider new evidence in 2019. Therefore, it was not arbitrary and capricious for him to ratify the Deeming Rule without considering the new evidence that appellants reference.

Furthermore, nothing in the record indicates that Commissioner Gottlieb, when he ratified the Deeming Rule, failed "to conduct an independent evaluation of

the merits," *Intercollegiate Broadcasting*, 796 F.3d at 117, or to make "a detached and considered judgment," *Doolin Sec.*, 139 F.3d at 213. Nor do appellants suggest that Commissioner Gottlieb was "actually biased." *Legi-Tech*, 75 F.3d at 709.

Because Commissioner Gottlieb effectively ratified the Deeming Rule, the court need not consider appellants' Appointments Clause objections to Commissioner Califf's ratification or to Associate Commissioner for Policy Kux's issuance of the Rule. Given that the Act does not mandate administrative exhaustion as a prerequisite to judicial review, the court also need not address the FDA's alternative contention that appellants forfeited their Appointments Clause claim by failing to raise it before the agency. *See Darby v. Cisneros*, 509 U.S. 137, 147 (1993); 21 U.S.C. § 387l (2018).

B.

Notwithstanding Commissioner Gottlieb's effective ratification, appellants contend that Appointments Clause violations are *per se* harmful, not curable by ratification, and so the court should consider the merits of their challenge to the Deeming Rule and the asserted "continuing prejudice" they suffer. Appellants' Br. 41–46. They suggest that a different notice-and-comment process might "affect the contents or even the existence of a new Deeming Rule" in view of the "new evidence accumulated since the Deeming Rule's issuance" and the "FDA's post-promulgation guidances . . . [that] have effectively, though only informally, eased some of the original Deeming Rule's effects." *Id.* at 42–45. In *Legi-Tech*, 75 F.3d at 708–09, this court rejected the view that prejudice must be presumed for Appointments Clause

violations. Subsequently, in *Intercollegiate Broadcasting*, 796 F.3d at 124, the court emphasized that "not every possible kind of taint is fatal" and that "speculative taint" such as the possibility that an invalid action was subsequently affirmed "simply out of agency solidarity" is insufficient.

Appellants demonstrate no "continuing prejudice." In the preamble to the Rule, the FDA acknowledged that there was uncertainty about the health effects of e-cigarettes, but concluded that the regulation of e-cigarettes "will still benefit public health" even if e-cigarettes "may eventually be shown to have a net benefit on or harm to public health at the population level." Deeming Rule, 81 Fed. Reg. 28,974, 28,984 (May 10, 2016). Absent record evidence of continuing prejudice, the court will take Commissioner Gottlieb's ratification "at face value and treat it as an adequate remedy." *Wilkes-Barre Hosp.*, 857 F.3d at 372 (quoting *Legi-Tech*, 75 F.3d at 709).

Contrary to appellants' suggestion that ratification of an action "merely moots an Appointments Clause claim, and the voluntary cessation exception to mootness applies," Appellants' Br. 46, this court has "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting the claim, resolves the claim on the merits by 'remedy[ing] [the] defect' (if any) from the initial appointment." *Guedes*, 920 F.3d at 13 (quoting *Wilkes-Barre Hosp.*, 857 F.3d at 371). Commissioner Gottlieb's ratification, for the reasons discussed, cured any potential Appointments Clause defect arising

from Associate Commissioner for Policy Kux's issuance of the Deeming Rule.

II.

Appellants further challenge the Act's preclearance pathway for modified risk tobacco products, which the Deeming Rule makes applicable to e-cigarettes, as violative of the First Amendment. This challenge is foreclosed by *Nicopure Labs, LLC*, 944 F.3d 267. There, the court found unpersuasive the objection that appellants make now, namely that the Deeming Rule violates the First Amendment because it places the burden on manufacturers to show that certain of their marketing claims are truthful and not misleading before they make them. *See id.* at 282–90; Appellants' Br. 60–64. The court sustained the preclearance pathway even when applied to modified-risk statements that manufacturers insist are "accurate" — such as claims that e-cigarettes contain less of or are free of specified ingredients — because "modified risk claims that might be technically accurate if viewed in isolation are in fact often misunderstood by consumers." *Id.* at 287.

Accordingly, we affirm the grant of summary judgment to the FDA.

Filed 02/11/2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MOOSE JOOCE, *et al.*, Plaintiffs, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 18-cv-203 (CRC)
RAVE SALON, INC. d/b/a JOOSIE VAPES, Plaintiff, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 18-cv-1615 (CRC)
JEN HOBAN d/b/a MASTERPIECE VAPORS, *et al.*, Plaintiffs, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 19-cv-372 (CRC)

MEMORANDUM OPINION

Responding to the public health risks posed by dramatic increases in vaping, especially among teens, the Food and Drug Administration in 2016 exercised its statutory authority to regulate electronic cigarettes.[1] It did so by issuing a final rule that deemed e-cigarettes to be "tobacco products" subject to regulation under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("Tobacco Control Act"). As a result of this "Deeming Rule," e-cigarettes are now subject to all the same types of regulations as traditional cigarettes, including restrictions on advertising, a ban on sales to minors, and requirements for nicotine warnings on packaging and advertisements.

In these consolidated cases, a collection of e-cigarette manufacturers and retailers challenge the Deeming Rule under the Appointments Clause and the First Amendment of the U.S. Constitution. First, they contend that the rule violates the Appointments Clause because the FDA official who signed it was neither a Senate-confirmed "principal officer" nor a duly appointed and supervised "inferior officer." The Court will reject Plaintiffs' challenge. Since the Deeming Rule was issued, two Senate-confirmed FDA Commissioners have ratified it. These ratifications were effective and cured any potential Appointments

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[1] This Opinion uses the term "e-cigarettes" to refer to all electronic nicotine delivery systems (ENDS) deemed to be tobacco products by the FDA, such as e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. *See* 81 Fed. Reg. 28,974, 29,028 (May 10, 2016); APP 306. These products include both "cigalikes," which mimic traditional cigarettes, and electronic devices that resemble everyday objects like flash drives.

Clause defect in the rule's issuance. Because it upholds the ratifications, the Court need not decide the merits of Plaintiffs' constitutional argument. Second, Plaintiffs argue that a pre-clearance requirement in the Tobacco Control Act now applicable to e-cigarettes violates the First Amendment because it places the burden on manufacturers to show that certain of their marketing claims are truthful and not misleading before they may make them. Since this case was filed, the D.C. Circuit issued an opinion in *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019), on a substantially similar claim. The Court finds that *Nicopure Labs* directly controls the question raised here and requires dismissal of Plaintiff's First Amendment challenge.

I. Background

The Tobacco Control Act gives the Secretary of Health and Human Services authority to regulate four enumerated categories of tobacco products—namely "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—as well as "any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). The HHS Secretary delegated this ability to "deem" tobacco products subject to the Act to the FDA Commissioner, who then sub-delegated that authority to the FDA's Assistant Commissioner for Policy ("ACP").[2] *See* 21 U. S.C. § 393(d)(2)(E)

[2] The position has since been renamed the Associate Commissioner for Policy as a part of an agency reorganization. This Opinion will use "ACP" to refer to both the Assistant Commissioner and the Associate Commissioner as those positions had the same relevant responsibility, namely to promulgate rules for the FDA under the Tobacco Control Act.

(permitting the HHS Secretary to delegate "such other functions as the Secretary may prescribe"); 2015 FDA Staff Manual Guide ("SMG") § 1410.10(1)(A)(14), J.A. 20 (delegation of authority to Commissioner); 2015 SMG § 1410.l0(l)(A), J.A. 19 (delegation of authority to ACP). The HHS Secretary expressly "reserve[d] the authority to approve regulations of the FDA" that "establish procedural rules applicable to a general class" or "present highly significant public issues." 2015 SMG § 1410.10(2)(A), J.A. 20. The FDA Commissioner, in turn, reserved the power to "continue to exercise all delegated authority." 2012 SMG § 1410.21(1)(G)(l), J.A. 43; *id.* § 1410.21(1)(A), J.A. 40.

In 2014, the FDA issued a Notice of Proposed Rulemaking, signed by the ACP, seeking comments on its plan to deem all tobacco products, including e-cigarettes, subject to regulation under the Tobacco Control Act. 80 Fed. Reg. 23,141 (Apr. 25, 2014), J.A. 141. At least one of the Plaintiffs here submitted a comment to the FDA, arguing that the proposed rule did not take into account the positive benefits of e-cigarette use (or "vaping") and did not appropriately tailor the regulations to the retail vaping industry in light of those benefits. Dennisa Moore, Joosie Vapes Inc., Comment Letter on Proposed Rule Deeming Tobacco Products to be Subject to the FDCA as amended by the Family Smoking Prevention and Tobacco Control Act (Aug. 6, 2014), J.A. FDA 125272-74. None of the more than 135,000 commenters challenged the ACP's authority to sign the proposed or final rule.

The final Deeming Rule, also signed by the ACP, was issued two years later. 81 Fed. Reg. at 28,973-

29,106, J.A. 252-384. In response to comments received on the proposed rule, the FDA considered "a robust body of scientific evidence about the uses and risks of e-cigarettes," *Nicopure Labs*, 944 F.3d at 273. This evidence included studies showing that e-cigarettes have the potential ability to help adults quit smoking conventional cigarettes, as well as studies indicating that young people who vape are more likely to begin smoking cigarettes. 81 Fed. Reg. at 29,036-41, J.A. 314-19. Balancing all the evidence, the FDA decided that risks of nicotine addiction for non-smoking youth outweighed the purported (and disputed) benefits of smoking cessation for adults. *Id.*

The Deeming Rule subjects e-cigarettes to the Tobacco Control Act and regulates their distribution, marketing, and labeling in two general ways: first, to reduce youth access, it bans sales to people under 18, requires ID checks for people under 26, and bans vending machine sales except in adult-only facilities, 81 Fed. Reg. at 29,057, J.A. 335; second, to inform consumers of the consequences of using the product, it requires packages and advertisements to contain a warning about the addictive nature of nicotine, 81 Fed. Reg. at 29,060, J.A. 338. In addition, several provisions in the Tobacco Control Act and its implementing regulations automatically applied to e-cigarettes upon issuance of the final rule, such as regulations on misbranding, ingredient lists, and free samples. 81 Fed. Reg. at 29,051, J.A. 329. One provision now applicable to e-cigarettes specifically challenged here is the Tobacco Control Act's pre-clearance requirement for "modified risk products." The Act places the burden on a manufacture to show that a tobacco product "is safer than other tobacco products" before it may market it as such. The Act

requires manufacturers "to substantiate such claims with evidence of their overall public health effects in advance of marketing, and to show that the proposed product as marketed will not mislead consumers as to its safety." *Nicopure Labs*, 944 F.3d at 284.

Since its issuance, the Deeming Rule has been ratified by two Senate-confirmed FDA Commissioners. In September 2016, FDA Commissioner Robert Califf ratified all of the agency's prior actions—including the Deeming Rule—as a part of a broad agency reorganization. J.A. 144. And after this litigation began, Commissioner Scott Gottlieb specifically ratified the Deeming Rule in April 2019. J.A. 231. He wrote:

> I hereby affirm and ratify the Deeming Rule as of the date it was published in the Federal Register on May 10, 2016, including all regulatory analysis certifications contained therein. I undertake this action based on my careful review of the rule, my knowledge of its provisions, and my close involvement in policy matters relating to this rule and its implementation, as well as its public health importance.

Id.

According to Plaintiffs, between the time of the Rule's promulgation and the Commissioners' ratifications, several additional studies showed that e-cigarettes may help adults quit smoking cigarettes and reduce the adverse health effects of cigarettes. *See* Pls.' Opening Br. at 31-33 (citing studies). Other studies, Plaintiffs say, showed that certain regulations, which result in higher e-cigarette prices,

have the effect of increasing the number of young people who smoke conventional cigarettes. *Id.* at 34. Also during this interim period, the FDA issued guidance documents that have adjusted some of the compliance deadlines in the final rule. *Id.*

Three sets of plaintiffs filed suit against the FDA alleging that the ACP was not appointed consistent with the Appointments Clause and, therefore, that her execution of the notice of proposed rulemaking and the final rule requires the court to "set aside" the Deeming Rule. *See, e.g.*, Moose Jooce Compl. ¶¶ 50-52 (quoting APA § 706(2)(A)). The parties have filed cross-motions for summary judgment on that issue. The Court held a hearing on October 22, 2019.

Plaintiffs also challenge the premarket review requirement for "modified risk tobacco products" under the First Amendment. *See, e.g.*, Moose Jooce Compl. ¶¶ 54-57. The Court stayed briefing on that issue to await the D.C. Circuit's ruling on a substantially similar issue in *Nicopure Labs*. *See* Minute Order, June 8, 2018. After the D.C. Circuit decided that case in early December 2019, the Court asked the parties whether additional briefing was required. Plaintiffs responded that further briefing is necessary because the issue decided by the Circuit is distinguishable from the issues raised here, while the FDA maintained that the Circuit's opinion clearly forecloses Plaintiffs' First Amendment claim. *See* Joint Status Report ("JSR") (Dec. 17, 2019), ECF 42.

II. Legal Standards

Summary judgment may be granted when "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law."

Fed. R. Civ. P. 56(a). Whether an agency action violates the Appointments Clause is a pure question of law that is properly decided by summary judgment. *See, e.g.*, *Estes v. U.S. Dep't of the Treasury*, 219 F. Supp. 3d 17, 38-39 (D.D.C. 2016); *see also* 5 U.S.C. § 706(2)(A) (requiring courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

III. Analysis

A. The Appointments Clause

1. Forfeiture

As a threshold matter, the FDA contends that Plaintiffs forfeited their Appointments Clause challenge by not raising it during the rule's notice-and-comment period. Gov't's Cross-Mot. for Partial Summ. J. 18-20. They agency is correct that generally "a party must initially present its comments to the [relevant] agency during the rulemaking in order for the court to consider the issue," *Tex Tin Corp. v. EPA*, 935 F.2d 1321, 1323 (D.C. Cir. 1991), and that "[s]imple fairness . . . requires as a general rule that courts should not topple over administrative decisions unless the administrative body . . . has erred against objection made at the time" of its decision, *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1150 (D.C. Cir. 2005) (quoting *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)). Appointments Clause claims are not immune from forfeiture. *See, e.g.*, *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 574 F.3d 748, 755-56 (D.C. Cir. 2009) *("Intercollegiate I")* (declining to consider an

Appointments Clause challenge not raised in opening appellate brief).

But courts have discretion to consider an untimely objection in "rare cases." *Freytag*, 501 U.S. at 879 (explaining, in the context of an agency adjudication, that avoiding "the disruption to sound appellate process entailed by entertaining objections not raised below does not always overcome what Justice Harlan called 'the strong interest of the federal judiciary in maintaining the constitutional plan of separation of powers.'" (quoting *Glidden Co. v. Zdanok*, 370 U.S. 530, 535-536 (1962) (Harlan, J., plurality opinion))). The Court chooses it exercise its discretion here. Unlike the appellant in *Intercollegiate I*, Plaintiffs have offered a reason to "depart from [the] normal forfeiture rule" and have offered a strong "justification for its delay." 574 F.3d at 756. Rulemaking is different from adjudication. *See Citizens Coal Council v. EPA*, 447 F.3d 879, 904 n.25 (6th Cir. 2006) (noting that forfeiture rules "should not be applied freely in both" rulemaking and adjudication contexts, "given the fundamental differences between the two endeavors"). Even though the forfeiture rules may apply in both contexts, *Styrene Info. & Research Ctr. v. Sebelius*, 994 F. Supp. 2d 71, 79 (D.D.C. 2013), and parties surely can forfeit arguments not made before the agency during a comment period, *see, e.g.*, *Advocates for Highway & Auto Safety*, 429 F.3d at 1150, the differences between rulemaking and adjudication counsel for a more lenient rule for unrepresented commenters who later wish to raise a separation-of-powers argument. Interested parties who are not attorneys or represented by counsel will naturally submit comments focusing on the rule's potential impact on them. It would be unfair to require them to

raise esoteric legal arguments with the agency or else be prevented later from arguing them to a court, especially when those arguments relate to important separation-of-powers issues. *Compare Intercollegiate I*, 574 F.3d at 755-56 (applying forfeiture rules to a *represented* party who failed to raise its Appointments Clause challenge in an agency adjudication or its opening brief *in federal court*). Any prejudice to the agency pales in comparison to the unfairness to Plaintiffs, particularly considering the FDA can rectify any Appointments Clause problem through an effective ratification after litigation is commenced, *see* Part III.B., *supra*.

In the absence of any indication that Plaintiffs were represented during the comment period, *see* Mot. Hr'g Tr. 27:11-15 (Oct. 22, 2019) (rough), the Court will exercise its discretion to consider their Appointments Clause claim.

2. Ratification

a. Merits

Plaintiffs contend that the Deeming Rule is invalid because it was promulgated by an FDA employee who had not been properly appointed as an officer of the United States and therefore lacked authority under the Appointments Clause to issue binding agency rules. But the Deeming Rule was ratified by two different FDA Commissioners after its publication in May 2016, and the D.C. Circuit has repeatedly held that an agency's ratification of a prior decision or action cures any potential Appointments Clause violation if "a properly appointed official has the power to conduct an independent evaluation of the merits and does so." *Intercollegiate Broad. Sys. v.*

Copyright Royalty Bd., 796 F.3d 111, 117 (D.C. Cir. 2015) *("Intercollegiate III")* (citing *FEC v. Legi-Tech, Inc.*, 75 F.3d 704 (D.C. Cir. 1996) and *Doolin Security Savings Bank v. Office of Thrift Supervision*, 139 F.3d 203 (D.C. Cir. 1998)); *see also Wilkes-Barre Hospital Co. v. NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017). It is the Plaintiffs' burden to present evidence—beyond the mere fact of ratification—"to suggest that the [agency] failed to conduct an independent evaluation of the merits or make a detached and considered judgment." *Wilkes Barre*, 857 F.3d at 371 (internal quotation marks omitted). An "independent judgment" does not require the ratifier to "return to square one" of the administrative process. Rather, "the better course" for courts is to take the ratification "at face value and treat it as an adequate remedy" for an Appointments Clause violation. *Legi-Tech*, 75 F.3d at 708-09 (refusing to "forc[e] the [agency] to start at the beginning of the administrative process"). The test is akin to "harmless error" under the APA. *Doolin*, 139 F.3d at 212-13 (explaining that the test for whether ratification is an adequate remedy "echoes the harmless error analysis" that "stems from the last sentence of § 706 of the Administrative Procedure Act: on judicial review of agency action, 'due account shall be taken of the rule of prejudicial error'"). Under this test, Plaintiffs bear the burden of providing evidence that the results of redoing the notice-and-comment process would yield a different result. *Id.*

In making that determination, the D.C. Circuit has instructed district courts not to look behind the ratification "notwithstanding the possibility" that it is merely a "rubberstamp" of the prior decision. *Intercollegiate III*, 796 F.3d at 118 n.1; *see also Doolin*, at 213 (holding that courts should find a ratification

effective even if it has "misgivings" about whether there was a "real fresh deliberation"). To succeed, Plaintiffs must provide evidence of "continuing prejudice" of the alleged error after the ratification, "and whether that degree of prejudice—if it exists—requires dismissal." *Legi-Tech*, 75 F.3d at 708; *see Intercollegiate III*, 796 F.3d at 124 ("[T]he subsequent proceeding is constitutionally suspect only if there is sufficient continuing taint arising from the first."). The Circuit has also cautioned against examining internal agency deliberations regarding the ratification "absent a contention" that the ratifier was "actually biased." *Legi-Tech*, 75 F.3d at 709.

Plaintiffs argue that the highly deferential standard of review that the Circuit established for agency ratifications in the cases cited above, all of which involved enforcement actions or adjudications, does not apply in the context of rulemakings like the one at issue here. Pls.' Reply/Opp'n 19-22. Rulemakings should be treated differently, Plaintiffs say, because the APA's procedural rulemaking requirements, including notice and opportunity for comment, continue until the moment of ratification. *Id.* The Court is not persuaded. Plaintiffs offer no reason—other than the existence of APA procedures—for differentiating between ratifications of rules and ratifications of enforcement decisions or agency adjudications. Adjudications are also covered by a host of APA procedures, yet the Circuit has applied its ratification doctrine to agency adjudications as well. *See Intercollegiate III*, 796 F.3d at 119. Up to that point, the Circuit had only approved ratifications in the enforcement context, but it rejected the notion that the type of agency proceeding mattered. *Id.* And it has since implied—though did not outright decide—

that rulemaking ratifications should be treated the same way. *See Guedes v. Bureau of Alcohol, Tobacco, Firearms and Explosives*, 920 F.3d 1, 12 (D.C. Cir. 2019) (accepting the parties' agreement that the ratification was effective to cure an Appointments Clause problem with a rulemaking).

Further, all the district courts in this District that have confronted the issue have applied the Circuit's ratification doctrine to rulemakings and have not required agencies to undergo the entire APA notice-and-comment processes anew before upholding otherwise effective ratifications. These courts have consistently held that a rulemaking "that would otherwise be unlawful due to procedural or technical defects . . . can be cured through a subsequent lawful ratification of that action." *Alfa Int'l Seafood v. Ross*, No. 17-cv-31, 2017 WL 3738397, at *1 (D.D.C. June 22, 2017) (Mehta, J.) (explaining that the court would accept a general post-litigation "statement [from the agency] acknowledging that [it] would re-promulgate the Rule in the same manner, even if it were required to re-start the notice and comment process"); *see also State Nat'l Bank of Big Spring v. Lew*, 197 F. Supp. 3d 177, 179-80 (D.D.C. 2016) (Huvelle, J.) (rejecting the notion that a ratification of a rulemaking requires the agency to redo the full APA's notice-and-comment procedures because, "regardless of the type of administrative action, [D.C. Circuit] decisions have consistently declined to impose formalistic procedural requirements before a ratification is deemed to be effective"); *Huntco Pawn Holdings, LCC v. U.S. Dep't of Defense*, 240 F. Supp. 3d 206, 232 (D.D.C. 2016) (Kollar-Kotelly, J.) (holding that that a ratification submitted to the court by a properly appointed official settles "any serious dispute

that the Final Rule, as published, reflects the decisions of the agency with authority to promulgate it").

Here, the ratifications by both Commissioner Califf and Commissioner Gottlieb cured any potential Appointments Clause issue with the promulgation of the Deeming Rule.

First, both ratifying Commissioners made "a detached and considered judgment" of the Deeming Rule. *See Wilkes-Barre*, 857 F.3d at 371. Commissioner Gottlieb ratified the Deeming Rule explicitly "based on [his] careful review of the rule, [his] knowledge of its provisions, and [his] close involvement in policy matters relating to this rule and its implementation." J.A. 231. He stated that he made a detached and considered judgment, and Plaintiffs have not provided any evidence to the contrary. The Court must therefore take Commissioner Gottlieb's ratification "at face value." *Legi-Tech*, 75 F.3d at 709. And while perhaps a closer question, Commissioner Califf s blanket ratification also meets the standards set by the D.C. Circuit. In *Wilkes-Barre*, the Circuit approved of a ratification of all "the actions taken during the period in which the Board lacked a valid quorum," 857 F.3d at 271, which is substantially similar to Commissioner Califf's ratification of "any actions taken . . . which in effect involved the authorities delegated herein prior to the effective date of this delegation," J.A. 144. Plaintiffs' counsel correctly noted at the hearing that the inference of "independent judgment" was stronger in *Wilkes-Barre* because the ratifier was the same person—though now validly appointed—who took the original actions. *See* Mot. Hr'g Tr. 5:17-6:3 (Oct. 22, 2019) (rough). But

again, the Circuit instructs that the independent judgment of the ratifiers should be taken "at face value," unless a plaintiff provides contrary evidence. *Legi-Tech*, 75 F.3d at 709. That evidence must be something more than the mere fact that the decision is being ratified. As Plaintiffs have not met that burden, the Court will not look behind Commissioner's Califf's blanket ratification either.

Second, Plaintiffs have not met their burden to show that any Appointments Clause violation was prejudicial in the sense that redoing the administrative process would yield a different result.[3] Plaintiffs' primary contention of error is that neither of the ratifying Commissioners discussed certain studies that were published between the issuance of the Deeming Rule and the later ratifications. Pls.' MSJ 30-37. By failing to acknowledge these intervening studies, Plaintiffs argue, the Commissioners violated the basic APA rule requiring

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[3] Citing *Legi-Tech*, Plaintiffs assert that a court must find that it is "virtually inconceivable" that a new administrative process would yield a different result before it could accept a ratification. Pls.' Mot. for Partial Summ. J. 30-31 ("Pls.' MSJ"); Pls.' Reply/Opp'n 25-27. But the Circuit did not create such a stringent test in *Legi-Tech*. In explaining why requiring an agency to redo the administrative process is not the correct remedy, the Circuit merely noted that "[e]ven were the Commission" to do so in that case, "it is virtually inconceivable that its decisions would differ in any way the second time from that which occurred the first time." *Legi-Tech*, 75 F.3d at 708 (citing cases that explain that "remand to the agency is an unnecessary formality where the outcome is clear"). The panel was merely explaining why, in light of "human nature," it would not generally be the case that the result of a redo of the administrative process would be different. *Id.* at 709. Based on that understanding, the Circuit held that "return[ing] to square one" is not required for an effective ratification. *Id.* at 708.

agencies to consider important aspects of the problem before them. But Plaintiffs conflate ratification doctrine with APA requirements prior to agency action. This explains why their principal reliance on *Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010), is misplaced. There, the Secretary of Interior issued a final decision to take into trust land on which an Indian tribe wished to conduct gaming operations based on a years-old legal opinion by the Department's Solicitor, while ignoring more recent evidence offered by the plaintiffs. The Circuit found that the Secretary had violated the APA by not considering relevant information *before* issuing his decision. *See id.* at 194-95. *Butte County* says little about the effectiveness of a ratification, however. Agency ratifications, which by definition come after a final action has been taken, are not governed by standard APA rules. As discussed, "regardless of the type of administrative action, [Circuit] decisions have consistently declined to impose formalistic procedural requirements before a ratification is deemed to be effective." *State Nat'l Bank*, 197 F. Supp. 3d at 184.

It bears noting that the effective ratification of the Deeming Rule does not prevent Plaintiffs from petitioning the FDA to repeal or amend the rule in light of the intervening studies. *See* 5 U.S.C. § 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."); *cf. CTS Corp. v. EPA*, 759 F.3d 52, 65 (D.C. Cir. 2014) (denying review based on the inability to comment on post-promulgation studies being added to the final record because plaintiff "could have petitioned the EPA for either reconsideration or a new rulemaking, or to reopen the notice-and-comment period."). If Plaintiffs are not satisfied with

the agency's response, they can seek judicial review. *See id.* §§ 702, 706; *see also Shipbuilders Council of Am. v. United States*, 868 F.2d 452, 456 (D.C. Cir. 1989) ("The denial of . . . a [section 553(e)] petition is subject to judicial review, provided that the petitioner can establish the requisite article III standing.").

In any case, the studies cited by Plaintiffs do not give the Court pause about whether a new notice-and-comment period would have yielded different results. *See Doolin*, 139 F.3d at 212-13.[4] The FDA considered studies that purported to show that e-cigarettes may be effective as smoking cessation devices and healthier in some respects than conventional cigarettes. But it nevertheless concluded that e-cigarettes "clearly have the potential to increase tobacco use and net health costs for the public as a whole." *Nicopure Labs*, 944 F.3d at 275 (citing 81 Fed. Reg. at 29,038). It is that ultimate conclusion which led the FDA to deem e-cigarettes subject to the Tobacco Control Act. Though the new studies Plaintiffs raise here may add to the quantum of evidence, there is no indication whatsoever that they alone would have upset the balance struck by the agency.

Finally, Plaintiffs have failed to show any "'continuing prejudice' from the [alleged] violations." *Wilkes-Barre*, 857 F.3d at 372 (quoting *Legi-Tech*, 75 F.3d at 708-09). The Court will not presume that any

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[4] Plaintiffs also cite the FDA's adjustment of compliance dates as evidence that a new rulemaking would yield a different result. Pls.' Reply/Opp'n 26-27. But while the Court does not discount the importance of compliance deadlines to the industry, that the FDA has extended them says little about whether it would reissue the substantive aspects of the rule.

taint from the alleged Appointments Clause violation continued after the rule was ratified. *Legi-Tech*, 75 F.3d at 708. And there is no indication that either of the ratifiers were "biased" by the alleged improper promulgation of the rule. *See Legi-Tech*, 75 F.3d at 709; *Wilkes-Barre*, 857 F.3d at 372. Without such a showing, the Court may not look behind the decision-making process that led to the ratifications. It must take them "at face value and treat [them] as an adequate remedy" for any potential Appointments Clause violation. *Legi-Tech*, 75 F.3d at 709.

The Court therefore finds the ratifications effective.

b. Ratification is Resolution on the Merits

Plaintiffs contend that their Appointments Clause challenge survives even if the ratifications were effective. They argue that ratifications in actions challenging a rulemaking merely moot the case (rather than operate as a decision on the merits) and that the voluntary-cessation exception to mootness applies to the ratifications here. Pls.' MSJ 37-40. Plaintiffs maintain that because there is no guarantee that the FDA will not simply continue its purportedly illegal practice of having the ACP sign final rules, the Court retains jurisdiction notwithstanding the effectiveness of the ratifications.

Again, Plaintiffs run headlong into D.C. Circuit precedent. The Circuit has "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting a claim, resolves the claim on the merits by remedying the defect (if any) from the initial appointment." *Guedes v. Bureau of Alcohol, Tobacco,*

Firearms and Explosives, 920 F.3d 1, 13 (D.C. Cir. 2019) (cleaned up); *see e.g.*, *Wilkes-Barre*, 857 F.3d at 371 (reaffirming that "[r]atification can remedy defects arising from the decisions of improperly appointed officials"). That rule make sense. Whether the FDA issues future rules through an improperly appointed officer is irrelevant to whether the Deeming Rule—the only rule challenged here—is valid. It is valid because it was ratified. Yet to be promulgated rules, that may or may not pose Appointments Clause concerns and may or may not affect these Plaintiffs, must await a different case. A challenge to them is too speculative in nature to be considered in this suit. Plaintiffs can (and should) raise potential Appointments Clause violations to the agency during such future rules' notice-and-comment periods to give the FDA the chance to confront any problems before they materialize.

Plaintiffs attempt to distinguish the well-established principle that ratification resolves Appointments Clause issues on the merits by highlighting that the relevant D.C. Circuit opinions all involved defenses to enforcement actions as opposed to independent, pre-enforcement challenges. Pls.' MSJ 37-38. That difference, to Plaintiffs, warrants rejecting the general rule and finding that the ratifications here merely moot their claim. *Id.* Plaintiffs primarily rely on the *Guedes* panel's discussion of ratification and mootness, *id.* (quoting *Guedes*, 920 F.3d at 12-17), but they read *Guedes* too far. That case involved President Trump's appointment of Acting Attorney General Whitaker under the Federal Vacancies Reform Act, after Attorney General Sessions resigned and before Attorney General Barr was nominated and confirmed.

Guedes, 920 F.3d at 9. Although most of the rulemaking process at issue took place under General Sessions, it was Acting General Whitaker who signed the final rule. After General Barr was confirmed, he announced—similar to Commissioner Gottlieb here—that he had "independently reevaluate[d]" the rule and the "underlying rulemaking record" and that he "personally c[a]me to the conclusion that it is appropriate to ratify and affirm the final rule." *Id.* at 9. The *Guedes* plaintiffs conceded that the ratification was effective, and the Circuit held—on appeal of a denial of preliminary injunctive relief—that "with th[e] act of ratification and the concession, [the plaintiff's] likelihood of success on the merits of his challenge to the rule based on Acting Attorney General Whitaker's role in its promulgation *reduces to zero*." *Id.* at 12 (emphasis added). The ratification meant that the plaintiffs would be unable to succeed on the merits because the ratification resolved the merits of their pre-enforcement Appointments Clause challenge. Full stop. Admittedly, the panel went on to address in dicta why the claim still lacked a likelihood of success *even if* they were to adopt the proposed analytical approach that ratification merely moots a claim. *Id.* at 14-17. But the panel assuredly did not adopt that approach, and its belt-and-suspenders mootness discussion does nothing to alter or undermine its fundamental holding, which this Court is bound to apply: Ratification resolves potential Appointments Clause errors on the merits. *Id.* at 13.

B. The First Amendment

Plaintiffs also challenge the rule under the First Amendment. *E.g.* Moose Jooce Compl. ¶¶ 54-57. They argue that the FDA's premarket review of e-cigarettes

that purport to reduce harm or the risk of disease is an impermissible restriction on commercial speech because it puts the burden on speakers (*i.e.*, e-cigarette manufacturers) to prove that their marketing materials are truthful and not misleading. *E.g.* Moose Jooce Compl. ¶¶ 55-56. The Court stayed the briefing on the First Amendment arguments pending the D.C. Circuits ruling in a case raising almost identically arguments. Once the Circuit issued that ruling in early December 2019, *see Nicopure Labs*, 944 F.3d 267 (D.C. Cir. 2019), the Court sought the views of the parties on whether Plaintiffs' arguments were now foreclosed or required further briefing. The parties disagreed on how to proceed: Plaintiffs argued that further briefing is required, while Defendants argued that *Nicopure Labs* resolved Plaintiffs' arguments.

The Court concludes that *Nicopure Labs* forecloses Plaintiffs' First Amendment claim. Plaintiffs maintain that *Nicopure Labs* is distinguishable because it merely "give[s] FDA the power to prohibit truthful, non-misleading speech if such speech is determined not to significantly reduce harm or to benefit the general public health" but does not "address[] at all the constitutionality of the Act's placement of the burden of proof entirely on the manufacturer-speaker, which is the focus of Plaintiffs' First Amendment claim." JSR, at 5. The Court disagrees. The Circuit expressly held that "[p]lacing an obligation on a manufacturer to demonstrate that an e-cigarette is in fact safer before it may market it as such easily" passes First Amendment scrutiny. *Nicopure Labs*, 944 F.3d at 284; *see also id.* at 288 (rejecting several industry arguments that it claimed FDA did not adequately considered because "[e]ach of

those suggestions seeks to place the onus on the government, rather than the manufacturers"). The Circuit quite clearly held that placing the burden on manufacturers to substantiate their marketing claims does not violate the First Amendment. Bound by that precedent, the Court holds that the Tobacco Control Act's premarket review provisions do not impermissibly burden speech.

IV. Conclusion

For the foregoing reasons, the Court will deny Plaintiff's Motion for Partial Summary Judgement and grant the FDA's Cross-Motion for Partial Summary Judgment on the Appointments Clause claim. The Court will also, *sua sponte*, grant Summary Judgment for the FDA on Plaintiffs' First Amendment Claim. A separate Order shall accompany this memorandum opinion.

s/ Christopher R. Cooper
CHRISTOPHER R. COOPER
United States District Judge

Date: February 11, 2020

Filed 02/11/2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MOOSE JOOCE, *et al.*, Plaintiffs, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 18-cv-203 (CRC)
RAVE SALON, INC. d/b/a JOOSIE VAPES, Plaintiff, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 18-cv-1615 (CRC)
JEN HOBAN d/b/a MASTERPIECE VAPORS, *et al.*, Plaintiffs, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 19-cv-372 (CRC)

ORDER

For the reasons stated in the accompanying Memorandum Opinion, it is hereby

ORDERED that [26] Plaintiffs' Motion for Partial Summary Judgment is DENIED. It is further

ORDERED that [28] Defendants' Cross-Motion for Partial Summary Judgment is GRANTED on the Appointments Clause Claim. It is further

ORDERED that Partial Summary Judgment is GRANTED, *sua sponte*, for Defendants on the First Amendment Claim.

This is a final appealable Order.

SO ORDERED.

s/ Christopher R. Cooper
CHRISTOPHER R. COOPER
United States District Judge

Date: February 11, 2020

U.S Const. art. II, § 2, cl. 2

He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

21 U.S.C. § 387a(b)

(b) Applicability

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

21 U.S.C. § 387j(a)(2)

(a) In general

* * * * *

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

21 U.S.C. § 387k(b)(2)(A)

(b) Definitions

* * * * *

(2) Sold or distributed

(A) In general

With respect to a tobacco product, the term "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers

believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

21 C.F.R. § 1100.1

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of tobacco product under section 201(rr) of the Federal Food, Drug, and Cosmetic Act, except accessories of such other tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act.

21 C.F.R. § 1100.2

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

81 FR 28973-01, 81 FR 28973-01,
2016 WL 2625201(F.R.)

RULES and REGULATIONS

DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2014-N-0189]

RIN 0910-AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Tuesday, May 10, 2016

AGENCY: Food and Drug Administration, HHS.

***28974** ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to deem products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. With this final rule, FDA is extending the Agency's "tobacco product" authorities in the FD&C Act to all other categories of products that meet the statutory

definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to reduce the death and disease from tobacco products. In accordance with the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

DATES: This rule is effective August 8, 2016. See section IV of this document regarding compliance dates for certain provisions.

* * * * *

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-10685 Filed 5-5-16; 8:45 am]

U.S. FOOD & DRUG
ADMINISTRATION

April 3, 2019

On May 10, 2016, the Food and Drug Administration published in the Federal Register a final rule entitled "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 81 Fed. Reg. 28,974 (the "Deeming Rule"). The authority under which the Deeming Rule was issued has been questioned in litigation. To resolve these questions, I hereby affirm and ratify the Deeming Rule as of the date it was published in the Federal Register on May 10, 2016, including all regulatory analysis certifications contained therein. I undertake this action based on my careful review of the rule, my knowledge of its provisions, and my close involvement in policy matters relating to this rule and its implementation, as well as its public health importance. This action is not intended to suggest any legal defect or infirmity in the promulgation of the Deeming Rule.

s/ Scott Gottlieb MD
Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Appendix F-2

State of Maryland
Montgomery County

On this 3rd day of April Scott Gottlieb personally appeared before me and acknowledged that he/she executed the foregoing instrument.

s/ Marguerite Constable
Notary Public

My commission expires: Jan. 10, 2021

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

DATE: 21 September 2016

TO: See Recipient List

FROM: Commissioner of Food and Drugs

SUBJECT: Delegation of Authority for General Redelegations of Authority from the Commissioner to Other Officers of the Food and Drug Administration (referenced in SMG 1410.21)

I am approving this delegation to amend the previous version.

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A. Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as referenced in the 1410 series of the Agency's Staff Manual Guides (SMGs). The Commissioner may continue to exercise all delegated authority referenced in these SMGs

B. The following officials are authorized to perform all delegable functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

1) Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco (OMPT).

2) Chief of Staff, Office of the Commissioner (OC)

3) Deputy Commissioner for Operations and Chief Operating Officer, Office of Operations (OO)

4) Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of Policy, Planning, Legislation and Analysis (OPPLA)

5) Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine (OFVM)

6) Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP)

7) Chief Scientist, Office of the Chief Scientist (OCS), OC

8) Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), OGROP.

C. The Federal Vacancies Reform Act of 1998 (Vacancies Reform Act) applies if the Commissioner dies, resigns, or is otherwise unable to perform the functions and duties of the Office of the Commissioner.

1) During an absence of the Commissioner that does not trigger the requirements of the Vacancies Reform Act, the first official in the following order who is available, or the official in the following list who has been designated by the Commissioner, to act shall lead the Agency (specific delegations provided below do not limit the general delegations provided

by this section to the designated officials who are authorized to perform all of -the delegable functions of the Commissioner):

a. Deputy Commissioner for Foods and Veterinary Medicine, OFVM.

b. Deputy Commissioner for Medical Products and Tobacco, (OMPT).

c. Chief of Staff, OC.

d. Deputy Commissioner for Operations and Chief Operating Officer, OO.

e. Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA.

f. Deputy Commissioner for Global Regulatory Operations and Policy, OGROP.

g. Chief Scientist, OCS, OC.

h. Associate Commissioner for Regulatory Affairs, ORA, OGROP.

i. Director, Center for Drug Evaluation and Research (CDER), OMPT.

2) When the Vacancies Reform Act applies, the Deputy Commissioner for Foods and Veterinary Medicine, OFVM, shall act as Commissioner unless the Deputy Commissioner for Foods and Veterinary Medicine, OFVM, does not meet the requirements of the Vacancies Reform Act or the President has directed someone else to act as Commissioner pursuant to the Vacancies Reform Act.

D. Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating them as "acting" or unless not legally permissible.

E. The following officials are authorized to perform all the functions of the officials under them in their respective offices and they may not further redelegate this authority:

1) Deputy Commissioner for Medical Products and Tobacco, OMPT.

2) Deputy Commissioner for Operations and Chief Operating Officer, OO.

3) Chief Scientist, OCS, OC.

4) Deputy Commissioner for Foods and Veterinary Medicine, OFVM.

5) Deputy Commissioner for Global Regulatory Operations and Policy, OGROP.

6) Associate Commissioner for Regulatory Affairs, ORA, OGROP.

7) Chief Counsel, Office of the Chief Counsel.

8) Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA.

F. The Deputy Commissioner for Medical Products and Tobacco, OMPT is authorized:

1) To make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with

Title 21, Code of Federal Regulations (21 CFR) 14.27.

2) To perform other associated advisory committee functions, e.g., establishing technical and scientific review groups (advisory committees); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

3) To approve conflict of interest waivers for Special Government Employees (SGEs) and regular government employees serving on advisory committees in accordance with 21 U.S.C. 379d-1 and 18 U.S.C. 208(b)1 and 208(b)(3), as amended.

4) To select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another Center.

5) To issue Federal Register (FR) Notices relating to advisory committee activities.

6) To further redelegate the authorities in paragraphs F.1-F.5 above to the Associate Commissioner for Special Medical Programs, Office of Special Medical Programs (OSMP), OMPT. In addition, in the event of absence or a vacancy in the position, the Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, is

designated to perform the functions in paragraphs F.1.-F.5 above.

7) Under Section 503(g)(4)(E)(ii) of the Federal, Food, Drug and Cosmetic Act (FFDCA), as added by Section 204 of the Medical Device User Fee Modernization Act of 2002 (MDUFMA), with respect to combination products the following: "During the review process, any dispute regarding the substance of premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the Agency Center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such Center. The Commissioner of Food and Drugs shall consult with the Director of the Office of Combination Products, OSMP, OMPT in resolving the substantive dispute."

G. The Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, Office of Policy (OP), OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, Office of Public Health Strategy and Analysis (OPHSA), OPPLA, are authorized:

1) To perform any of the functions of the Commissioner with respect to the issuance of FR notices and proposed and final regulations of the Food and Drug Administration. This authority may not be further redelegated.

2) To issue responses to the following matters under part 10 of 21 CFR as follows and these

officials may not further redelegate this authority:

a. Requests for waiver, suspension, or modification of procedural requirements under Section 10.19 of 21 CFR.

b. Citizen petitions under Section 10.30 of 21 CFR.

c. Petitions for reconsideration under Section 10.33 of 21 CFR.

d. Petitions for stay under Section 10.35 of 21 CFR.

e. Requests for advisory opinions under Section 10.85 of 21 CFR.

3) With respect to any matter delegated to the Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, OP, OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, OPHSA, OPPLA, under this paragraph, the Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, OP, OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, OPHSA, OPPLA, are authorized to perform the functions of the Commissioner under Section 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of 21 CFR and of a Deputy Commissioner under Section 10.206(g) and (h) of 21 CFR. These authorities may not be further redelegated.

4) Under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. The Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA, the Associate Commissioner for Policy, OP, OPPLA, and the Associate Commissioner for Public Health Strategy and Analysis, OPHSA, OPPLA, may further redelegate this authority.

5) To make all determinations and findings under 21 CFR Part 15, and to waive, suspend, or modify any procedural requirements related to Part 15 under Section 10.19 of 21 CFR.

H. The Associate Director for Policy, Office of Regulatory Policy, CDER, OMPT, is authorized:

1) To waive or reduce prescription drug user fees in situations where he or she finds that such a waiver or reduction: (1) is necessary to protect the public health under Section 736(d)(1)(A) of the FFDCA (21 U.S.C. 379h(d)(1)(A)), as amended; (2) is necessary because the fee would present a significant barrier to innovation under Section 736(d)(1)(B) of the FFDCA (21 U.S.C. 379h(d)(1)(a)), as amended; or (3) is appropriate under Section 736(d)(1)(D) of the FFDCA (21 U.S.C. 379h(d)(1)(D)), as amended because the applicant involved is a small business submitting its first human

drug application. These authorities may not be further redelegated.

2) To act upon requests for consideration of any user fee decisions under Section 735 of the FFDCA (21 U.S.C. 379h), other than decisions on fee-exceed-the cost waiver requests, made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These authorities may not be further redelegated.

I. The Director, Policy and Regulations Staff, Office of the Center Director, Center for Veterinary Medicine (CVM), OFVM is authorized:

1) To waive or reduce animal drug user fees in situations where he or she finds that such a waiver or reduction: (1) is necessary because the fee would present a significant barrier to innovation under Section 740(d)(1)(A) of the FFDCA (21 U.S.C. 379j-12(d)(1)(A)), as amended; (2) is necessary because the drug application or supplemental application is intended solely for use of the animal drug in medicated feeds under Section 740(d)(1)(C) of the FFDCA (21 U.S.C. 379j-12(d)(1)(C)), as amended; (3) is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for minor use or minor species indications under Section 740(d)(1)(D) of the FFDCA (21 U.S.C. 379j-12(d)(1)(0)), as amended; or (4) is appropriate under Section 740(d)(1)(E) of the FFDCA (21 U.S.C. 379h(d)(1)(E)), as amended because the applicant involved is a

small business submitting its first animal drug application. This authority may not be redelegated.

2) To waive or reduce generic animal drug user fees in situations where he or she finds that such a waiver or reduction is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for minor use or minor species indications under Section 741(d) of the FFDCA (21 U.S.C. 379j-21(d)), as amended.

3) Under any of the above cited provisions of Section 740 and 741 of the FFDCA, to act upon requests for reconsideration of decisions made. This authority may not be redelegated.

J. The Associate Director for Policy and Communications, Office of the Director, CVM, OFVM, is authorized to act upon requests for reconsideration of decisions made under any provision of Sections 740 and 741 of the FFDCA, except for those decisions that pertain to fee-exceed-the cost waiver requests. This authority may not be further redelegated.

K. The Deputy Commissioner for Operations and Chief Operating Officer, OO, is authorized to perform the functions of the Commissioner under:

1) Section 736(d)(1)(c) of the FFDCA (21 U.S.C. 379h(d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situations where he or she finds that "the fees will exceed the anticipated present and future

costs." The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, Office of Finance, Budget and Acquisitions (OFBA), OO.

2) Section 740(d)(1)(B) of the FFDCA, to waive or reduce animal drug user fees, for waiver or reduction requests made on the basis that the fees assessed exceed the costs to FDA for reviewing applications. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budge [sic] and Acquisitions, OFBA, OO.

3) Section 736(c)(4) of the FFDCA, as amended by the Prescription Drug User Fee Act Amendments of 2002, to establish application, product, and establishment fees under Section 736(a), based on the revenue amounts established under Section 736(b) and the adjustments under 736(c). The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

4) Section 738 of the FFDCA, as added by the MDUFMA, to adjust and set fee rates for medical device applications each year. The

Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

5) Section 740(c)(4) of the FFDCA, to adjust and set new and supplemental animal drug application fees, animal drug sponsor fees, animal drug product fees, and animal drug establishment fees. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

6) Section 741(c)(3) of the FFDCA, to adjust and set abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees. The Deputy Commissioner for Operations and Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

7) Section 919(b)(6)) [sic] of the FFDCA (21 U.S.C. 387s(c)(6)), to notify each manufacturer and importer of tobacco products subject to this Section of the amount of the quarterly assessment due for such products. The Deputy Commissioner for Operations and Chief Operating Officer, OO,

may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

8) Under any fees-exceed-cost user fee waiver or reduction sections of the FFDCA noted above, act upon requests for reconsideration of decisions made by such officers. This authority may not be redelegated.

L. The Chief Scientist, OCS, OC, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

M. The Deputy Commissioner for Operations and Chief Operating Officer, OO, is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

N. The following officials are authorized to deny a request to issue an emergency use authorization (EUA) under Section 564 of the FFDCA, and to consult under Section 564(c) of the FFDCA, requiring "consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible

and appropriate given the circumstances of the emergency involved)" prior to issuing an EUA:

1) Chief Scientist, OCS, OC.
2) Deputy Commissioner for Medical Products and Tobacco, OMPT.
3) Director, Center for Biologics Evaluation and Research (CBER), OMPT.
4) Director, Center for Drug Evaluation and Research (CDER), OMPT.
5) Director, Center for Devices and Radiological Health (CDRH), OMPT.

O. The following officials are authorized to issue the final decision regarding the disqualification of a clinical investigator, i.e., the investigator's eligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b):

1) Deputy Commissioner for Medical Products and Tobacco, OMPT.
2) Chief Scientist, OCS, OC.
3) Associate Commissioner for Special Medical Programs, OMPT.

P. The following officials are authorized to sign a consent agreement between the FDA and a clinical investigator regarding the disqualification of the clinical investigator, resulting in the clinical investigator's ineligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b) and containing a binding provision that disqualification pursuant to the consent

agreement has the same legal effect as being disqualified pursuant to the relevant regulation after a Part 16 Hearing. These officials may not further redelegate this authority.

1) Director, CBER, OMPT.
2) Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT.
3) Director, CDER, OMPT.
4) Director and Deputy Director, Office of Compliance (OC), CDER, OMPT.
5) Director and Deputy Director, Division of Scientific Investigations (DSI), OC, CDER, OMPT.
6) Director, CVM, OFVM.
7) Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM, OFVM.
8) Director, Division of Compliance, OSC, CVM, OFVM.
9) Director, CDRH, OMPT.
10) Deputy Director for Science, CDRH, OMPT.
11) Director, Office of Compliance (OC), CDRH, OMPT.
12) Deputy Director for Medical Affairs, OC, CDRH, OPMT.

2. RE-DELEGATION.

Except as otherwise provided, these Officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

A. These delegations become effective upon date of signature.

B. In addition, I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

s/ Robert M. Califf
Robert M. Califf, M.D.
Commissioner of Food and Drugs

Recipients:

- Chief Counsel, OCC, OC
- Chief Scientist, OCS, OC
- Deputy Commissioner for Foods and Veterinary Medicine, OFVM
- Deputy Commissioner for Global Regulatory Operations and Policy, OGROP
- Deputy Commissioner for Medical Products and Tobacco, OMPT
- Deputy Commissioner for Operations and Chief Operating Officer, OO
- Deputy Commissioner for Policy, Planning, Legislation and Analysis, OPPLA
- Associate Commissioner for Regulatory Affairs, ORA, OGROP
- Associate Commissioner for Special Medical Programs, OMPT

- Associate Commissioner for External Affairs, OEA, OC
- Center Directors
- Center Executive Officers
- Component Delegation Control Officers
- Principal Delegation Control Officer