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UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, ACTION ON SMOKING AND HEALTH, AMERICAN MEDICAL ASSOCIATION, and NATIONAL MEDICAL ASSOCIATION, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; U.S. FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, in her official capacity as Acting Commissioner of Food and Drugs; CENTER FOR TOBACCO PRODUCTS; MITCH ZELLER in his official capacity as the Director, Center for Tobacco Products. Defendants.	Case No. 4:20-cv-4012-KAW **FEDERAL DEFENDANTS' REPLY IN SUPPORT OF SECOND MOTION TO DISMISS (DKT. 53)**

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PRELIMINARY STATEMENT

On April 29, 2021, the United States Food and Drug Administration (FDA) responded to Plaintiffs' citizen petition, determined that menthol should be added to the tobacco product standard known as "the flavor ban," and commenced drafting a notice of proposed rulemaking (NPRM) to do so. These official agency decisions are significant events in federal rulemaking, and they are neither tentative nor indefinite. Indeed, FDA expressed its intent to make this proposed rule one of the agency's highest priorities, and set an expected date for publication of the NPRM within twelve months. Importantly, FDA's actions encompassed *all* of the relief Plaintiffs could legally obtain on their unreasonable delay claims under the Administrative Procedure Act (APA), 5 U.S.C. § 706(1).

Nevertheless, in an effort to oversee the agency's rulemaking process, Plaintiffs seek continued "judicial oversight and intervention." To that end, Plaintiffs demand action far beyond what is legally required by the Tobacco Control Act or FDA's regulations, mischaracterize Defendants' positions as claims of "unfettered discretion," and assert "voluntary cessation," an inapplicable mootness exception. Throughout their brief, Plaintiffs also continue to advance an overly simplistic view of rulemaking, ignoring both the many steps involved in initiating and developing a proposed rule, and the importance of drafting a detailed and comprehensive NPRM for a complex public health regulation like the one here. None of Plaintiffs' arguments have merit. Moreover, overseeing the notice-and-comment rulemaking process is not an appropriate role for the Court, and not an efficient use of judicial resources. Instead, the Court should dismiss the case as moot and for failure to state a claim.

ARGUMENT

I. Defendants Have Met Their Burden on Mootness by Establishing That Plaintiffs Received All Legally-Available Relief.

Plaintiffs' Second Amended Complaint (First Supplement) presents only two claims: that FDA unreasonably delayed addressing menthol as a characterizing flavor in cigarettes (Claim I), and that FDA unreasonably delayed responding to Plaintiffs' citizen petition (Claim II). *See* 2d. Am. Compl. (Supp.), Dkt. 52. Section 706(1) of the APA authorizes a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed." A court's ability to compel such action, however, "is carefully circumscribed to situations where an agency has ignored a specific legislative command."

Hells Canyon Pres. Council v. U.S. Forest Serv., 593 F.3d 923, 932 (9th Cir. 2010) (following *Norton v. S. Utah Wilderness All. (SUWA)*, 542 U.S. 55 (2004)). As the Supreme Court has explained, "the only action that can be compelled under the APA is action legally *required*." *SUWA*, 542 U.S. at 63 (emphasis in original). Applying that standard here, only two agency actions can be compelled on Plaintiffs' claims: a "determination of whether to *modify* the [tobacco product] standard [in 21 U.S.C. § 387g(a)(1)(A)], which may include adding menthol to the flavor ban," Order, Dkt. 34 at 4 (emphasis in original); and a response to the citizen petition. These two actions are now complete, and the case should be dismissed.

Plaintiffs attempt to avoid dismissal on mootness by seeking additional agency action, but mootness focuses only on available relief, *i.e.* effective relief that "can be granted." *Feldman v. Bomar*, 518 F.3d 637, 642 (9th Cir. 2008). But Plaintiffs' new requested relief cannot be granted on Plaintiffs' unreasonable delay claims because it is not legally required. For this reason, Plaintiffs also fail to state a claim upon which relief could be granted. Plaintiffs' newly-articulated demands boil down to two requests: that the Court "order defendants to issue a NPRM by a date certain… [and] order defendants to complete the rulemaking process by a reasonable date." Opp., Dkt. 58 at 3. Yet, none of those requests originate from the operative complaint, which asked for no such relief. *Compare* Opp., Dkt. 58 at 13 (claiming "the amended complaint does seek additional relief" set out in three specific bullet points) *with* 2d Am. Compl. (Supp.), Dkt. 52 at 50-51 ("Requested Relief") (omitting that additional language) *and* Compl. Dkt. 1 at 44 (using exactly the same words as Dkt. 52, the Second Amended Complaint, to describe requested relief in June 2020).

Even if Plaintiffs had properly asserted their additional requests for relief, their claims would still fail because that relief is not available under § 706(1) of the APA. As explained above, the only actions that can be compelled under § 706(1) are actions that are legally required. *Hells Canyon Pres. Council*, 593 F.3d at 932. Here, Plaintiffs have not identified any legal requirement that Defendants publish an NPRM when granting a citizen petition or issuing a determination that the flavor ban should be changed, much less a command that Defendants complete rulemaking to ban menthol. Nor is there any authority requiring that either action be completed on a particular timeline. Indeed, this Court has already held that FDA was not required to ban menthol under the Tobacco Control Act. Order, Dkt. 34 at 4, 8. Plaintiffs

should not be permitted to circumvent that Order by inventing new statutory and regulatory requirements.

A. The Tobacco Control Act Leaves the Form of a "Determination" under 21 U.S.C. § 387g(a)(5) to FDA's Discretion.

Plaintiffs sought a determination under 21 U.S.C. § 387g(a)(5) about whether the flavor ban should be modified to include menthol. 11/5/20 Tr., Dkt. No. 33 at 4:18-22; 5:7-15, 21-24; 14:18-22 (clarifying Claim I at the November 5, 2020, hearing). FDA made that determination in its response to Plaintiffs' citizen petition. 2d JCMS, Attach. A, Dkt. 51-1 at 14. Plaintiffs now insist, contrary to their position at the hearing, that "the law requires such a determination to be in a more actionable form," specifically that it "must be accompanied by implementing action, *i.e.*, publication of a NPRM in the Federal Register." Opp., Dkt. No. 58 at 9, 22. This is an about-face from Plaintiffs' acknowledgement that, "yes, perhaps the Federal Register would be a way to do it, but of course, [Defendants] *can publish their determination in any particular way they want:* Email, some sort of letter to us or some sort of response to the citizen petition." 11/5/20 Tr., Dkt. No. 33 at 9:15-19 (emphasis added). But aside from Plaintiffs' shifting positions, the fact remains that there is no such publication requirement in the statute.

Plaintiffs contend that a determination under § 387g(a)(5) "to implement a new or modified tobacco product standard" must be "accompanied" by an NPRM. Opp., Dkt No. 58 at 21-22. That is wrong. Section 387g(a)(5) contains no language whatsoever indicating such a requirement:

> (5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

On the contrary, this provision is wholly silent on the form of a determination, regardless of whether FDA's periodic evaluation leads the agency to determine that a tobacco product standard should be changed. *Id.* The Court should reject Plaintiffs' attempt to add a requirement that is not there, for "in any field of statutory interpretation, it is [a court's] duty to respect not only what Congress wrote, but, as importantly, what it didn't write." *Virginia Uranium Inc. v. Warren*, 139 S. Ct. 1894, 1900 (2019).

Given the absence of any textual support in § 387g(a)(5), Plaintiffs instead turn to a subsection that authorizes FDA to "adopt" *new* tobacco product standards—specifically standards "*in addition* to those in paragraph (1)," which includes the flavor ban. *See* Mot., Dkt. 53 at 15 (discussing the application of 21 U.S.C. § 387g(a)(3)(B)(ii)). That subsection explicitly excludes the flavor ban from any requirement for newly adopted standards. *Id.* Nevertheless, Plaintiffs argue that it is acceptable to rely on § 387g(a)(3) for two reasons, both of which lack merit.

First, Plaintiffs argue that FDA uses rulemaking both when adopting a new tobacco product standard and when revising an existing one. *See* Opp., Dkt. 58 at 22 (arguing "the process… is the same," and citing Defendants' reference to notice-and-comment rulemaking). But the fact that § 387g(c) directs rulemaking when FDA adopts a new tobacco product standard or revises an existing one is irrelevant to the *form* of a determination under § 387g(a)(5). Moreover, nothing in § 387g(c) requires the issuance of an NPRM at the time FDA makes a determination under § 387g(a)(5). Nor does § 387g(c) impose timing requirements for issuing an NPRM after FDA determines that a tobacco product standard should be changed.

Second, Plaintiffs attempt to shift focus from their misplaced reliance on § 387g(a)(3) by arguing that Defendants "offer no explanation of why determination would mean something different in the context of amendment rather than an initial rulemaking." Opp., Dkt. 58 at 22. But it was Congress that set forth a separate provision authorizing FDA to "adopt" new standards without making that provision applicable to revisions of the flavor ban, and without adding any similar language in § 387g(a)(5). As the Supreme Court has explained, "we generally presume that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another." *Intel Corp. Inv. Policy Comm. v. Sulyma*, 140 S. Ct. 768, 777 (2020) (*quoting BFP v. Resolution Tr. Corp.*, 511 U.S. 531, 537 (1994)). Moreover, it is simply not possible to find a legally-required action regarding the flavor ban in a provision that explicitly *excludes* it.

Additionally, even for *new* tobacco product standards, Plaintiffs have misinterpreted the statutory text and inserted a requirement that simply is not there. Plaintiffs' focus only on the first part of

§ 387g(a)(3)(B)(ii) in isolation, *see* Opp., Dkt. 58 at 22-23, but the remainder of that sentence provides important context: "[i]n the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, . . . any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence… ." 21 U.S.C. § 387g(a)(3)(B)(ii). In other words, a proposed rule is simply a condition precedent for providing FDA with evidence when objecting to a new tobacco product standard. *Id.* Even if the provision applied to revisions of the flavor ban (which it does not), it would only mean that persons objecting to the proposed tobacco product standard have a right to present evidence whenever an NPRM is published. That provision does not define "determination," nor does it set forth a requirement for immediate publication of an NPRM. *Id.* Thus, while Plaintiffs correctly state that statutes must be read as a whole, Opp., Dkt. 58 at 23, Plaintiffs fail to apply that principle to their interpretation of § 387g(a)(3)(B)(ii). The result is something far removed from a plausible interpretation of the statute, much less a clear mandate for legally-required action by FDA.

Finally, Plaintiffs describe the rulemaking process as "FDA's ultimate determination of whether to ban menthol in cigarettes." *See* Opp, Dkt. 58 at 12. To the extent that refers to 21 U.S.C § 387g(a)(5), it is also wrong. As explained, FDA's determination was set forth in its citizen petition response, and FDA is implementing that determination through the rulemaking process. By conflating these actions, Plaintiffs again attempt to insert new terms into the statute that are not there. But as the Supreme Court has explained, statutes cannot be read to add terms and impose meaning that is not found in the statutory text. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania,* 140 S. Ct. 2367, 2381 (2020) ("It is a fundamental principle of statutory interpretation that absent provisions cannot be supplied by the courts.") (quotation omitted). Contrary to Plaintiffs' arguments, the Tobacco Control Act leaves the form of any determination to FDA's discretion.

B. The Citizen Petition Regulation in 21 C.F.R. § 10.30(e) Leaves Appropriate Implementing Action to FDA's Discretion.

Plaintiffs allege that FDA cannot approve a citizen petition without publication of a "notice" in the Federal Register, and suggest that "proposing a rule" in the Federal Register constitutes the only appropriate implementing action within the meaning of the citizen petition regulation. *See* Dkt. 52 at

¶¶ 144, 168. However, the regulation at issue, 21 C.F.R. § 10.30(e)(2)(i), provides only that when FDA approves a citizen petition, "the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval." In the opening brief, Defendants explained that the "e.g." signal in the regulation merely indicates an example of appropriate implementing action, rather than a requirement for a specific action. Mot., Dkt. 53 at 6, 16-18.

In response, Plaintiffs do not engage with the text of the regulation, but instead rely on conclusory assertions that the regulation requires "meaningful action to effectuate the alleged approval," and that "[a]bsent a final rule, such [implementing] 'action' is meaningless." Opp., Dkt. 58 at 23, 24. But Plaintiffs' conclusory assertion is wholly divorced from the text of regulation, which nowhere mentions "meaningful action to effectuate" an approval or suggests the issuance of a final rule when approving a petition that requests rulemaking. *See* 21 C.F.R. § 10.30(e)(2)(i). Instead, Plaintiffs pivot to a case interpreting a provision in the Endangered Species Act that sets a twelve-month deadline for the Interior Secretary's final finding on a species' conservation status. *See* Opp., Dkt. 58 at 23 (citing *Conservation Force, Inc. v. Jewell*, 733 F.3d 1200, 1204 (D.C. Cir. 2013)). But the Endangered Species Act is inapposite. That statute provides that the Interior Secretary "shall promptly publish in the Federal Register a general notice and complete text of a proposed regulation to implement" the decision to grant action requested in a petition. 16 U.S.C. § 1533(b)(3)(B)(ii). FDA's citizen petition regulation, however, only requires FDA to take "appropriate action" to implement a citizen petition approval. 21 C.F.R. § 10.30(e)(2)(i). Unlike the Endangered Species Act, the citizen petition regulation does not require FDA to "promptly publish in the Federal Register… the complete text of a proposed regulation." Aside from these critical differences, an entirely different (and irrelevant) statutory scheme simply cannot provide a clear legal mandate for FDA's action.

Instead, the Court must look to the plain meaning of 21 C.F.R. § 10.30(e)(2)(i), which leaves "appropriate action" implementing a citizen petition approval to FDA's discretion. *See* Mot., Dkt. 53 at 17, citing *Minnick v. Comm'r*, 796 F.3d 1156, 1159 (9th Cir. 2015). Here, Acting Commissioner Woodcock's memorandum directing FDA to promptly begin drafting a proposed rule was an appropriate action. Upon its issuance, the memorandum initiated the subsequent actions necessary to prepare the proposed rule over the next twelve months, including work on the NPRM's preamble to provide a

explain the support for the proposed standard; related economic and environmental analyses evaluating the potential impacts of the proposed standard; and listing of an anticipated NRPM publication date in the Spring 2021 Unified Agenda of Regulatory and Deregulatory Actions. *See* Mot., Dkt. 53 at 6-8 (explaining the action and the regulatory process for adding menthol to the flavor ban)[1] *and* Spring 2021 Unified Agenda (an NPRM is expected in April 2022).[2] Although Plaintiffs are dissatisfied with this implementing action, the memorandum constituted an "appropriate action" under the citizen petition regulation, and nothing more was required of FDA.

C. Plaintiffs' Discussion on "Effective Relief" Ignores the Need for Legally-Required Action.

Throughout their opposition, Plaintiffs overlook the need to state a claim for legally-required relief to survive both a mootness challenge under Rule 12(b)(1) and a sufficiency challenge under Rule 12(b)(6). Relying on various cases, Plaintiffs argue that "the Court can grant plaintiffs several forms of effective relief." *See* Opp., Dkt. 58 at 12-16. But none of the cases in Plaintiffs' opposition address the situation at issue here, where Plaintiffs seek to compel agency action that is not legally-required.

Indeed, Plaintiffs' cases on "effective relief" did not involve § 706(1) claims at all, much less whether those claims could survive a mootness or sufficiency challenge. Rather, those cases involved constitutional challenges that addressed an individual's continued standing to challenge the law following changed personal circumstances. For example, in *McCormack v. Herzog*, the plaintiff had been offered criminal immunity for an abortion, but still had standing to pursue a facial constitutional challenge to state law abortion restrictions. *See* 788 F.3d 1017, 1024-25 (9th Cir. 2015). Similarly, in *Leigh v. Salazar*, the plaintiff sought to photograph a Bureau of Land Management wild horse roundup, but still had standing to pursue her First Amendment right to document future roundups after the event ended. 677 F.3d 892 (9th Cir. 2012). Likewise, in *Fikre v. FBI*, the plaintiff continued to have standing to challenge the constitutionality of the government's process for the "Do Not Fly List," even after he

[1] Page 8 of Defendants' Motion incorrectly cited page 19 of the General Accounting Office, *GAO-09-205, Federal Rulemaking* 11-12 (2009). The referenced material is located on page 13. *See* Opp., Dkt. 58 at 12, n.7 (identifying the citation error).

[2] The Spring 2021 Unified Agenda, posted June 14, 2021, is the current version of the 2019 Unified Agendas discussed in the complaint, Dkt. 52 at ¶¶ 131-139. FDA's proposed rule on the tobacco product standard to prohibit use of menthol as a characterizing flavor in cigarettes is available at: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0910-AI60

was personally removed from the list. 904 F.3d 1033 (9th Cir. 2018). Thus, none of these cases address the situation at issue here, where Plaintiffs seek to compel an agency action that is not legally required.

By contrast, in another section of their opposition, Plaintiffs rely on *Conservation Force*—a case which did in fact address unreasonable delay under § 706(1). But that case supports Defendants' arguments. There, the court held that once an agency completes all the legally-required action by satisfying the relevant rulemaking benchmark, the plaintiffs' unreasonable delay claims for the completion of that rulemaking benchmark becomes moot.733 F.3d at 1204. So too here, Plaintiffs' undue delay claims have become moot, because FDA has completed all the legally-required action that Plaintiffs could obtain on their claims.

Plaintiffs attempt to distinguish Defendants' cases, arguing that "there was no further action that could be taken by the government." Opp. Dkt. 58 at 15. But this argument misses the point, because the correct question is whether further action can be *legally required* from the government. *Hells Canyon Pres. Council,* 593 F.3d at 932. As explained, the answer to that question is no. Plaintiffs' fallacy is particularly well-illustrated in their attempt to distinguish *Center for Biological Diversity v. Kempthorne*. Plaintiffs claim that *Kempthorne* is distinguishable because they "have always sought broader relief than a decision on their citizen petition, up to and including a menthol ban." *See* Opp., Dkt. 58 at 15, *discussing* 498 F. Supp. 2d 293, 297 (D.D.C. 2007). But that statement of relief, even if true, does not distinguish this case from *Kempthorne*. In *Kempthorne*, the plaintiffs similarly sought a final rule, as well as judicial oversight over the rulemaking process after the agency granted the plaintiffs' petition. *See* 498 F. Supp.2d at 296-297. Nevertheless, the court dismissed the case on mootness grounds because the plaintiffs' complaint failed to identify any additional *legally-required* action that had been delayed. *Id.* As in *Kempthorne*, Plaintiffs have failed to identify any additional *legally-required* action that has been delayed and thus their unreasonable delay claims should be dismissed.

D. Even if Legally Required, the NRPM Cannot Be a Basis for an Unreasonable Delay Claim Now, Because It Is Not Delayed.

On April 29, 2021, FDA determined the flavor ban should be changed to include menthol and that the agency should issue a proposed rule prohibiting menthol as a characterizing flavor in cigarettes.

Mot., Dkt. 53 at 5-6. Plaintiffs have repeatedly argued that FDA should have banned menthol long before that date. *See, e.g.,* Opp., Dkt. 58 at 10. But FDA clearly was not legally required to undergo rulemaking on a menthol ban before April 29, 2021, Order, Dkt. 34 at 8, and an unreasonable delay claim cannot begin before the agency has a duty to act. *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir.1992) (considering when the agency takes on a duty to act).

Plaintiffs filed their new complaint a mere twenty-two days after FDA decided to draft the NPRM. *See* Sec. Am. Compl. (Supp.), Dkt. 52 (filed May 21, 2021). On September 16, 2021 (the hearing date for this motion), a total of only four months and eighteen days will have passed. At that time, the NPRM will still be on the schedule that FDA set when it made its determination to add menthol to the flavor ban. *See* Mot. Dkt. 53 at 6 (FDA announced an expected twelve-month schedule on April 29, 2021). That is not sufficient time to state a claim for unreasonable delay, and indeed, all the cases that Plaintiffs cite for delay involved much longer periods. *See, e.g.,* Opp. Dkt. 58 at 20 *citing Pub. Citizen Health Res. Group v. FDA*, 724 F. Supp. 1013, 1020 (D.D.C. 1989) (noting that five years had passed since the agency created a duty by deciding to take on a particular rulemaking). The Ninth Circuit has explicitly held that actionable unreasonable delay claims "involv[e] delays of years, not months." *Pac. Gas & Elec. v. FERC* (*In Re Cal Power Exch. Corp.)*, 245 F.3d 1110, 1125 (9th Cir. 2001). Plaintiffs mistakenly dismiss that controlling law in a footnote, calling it "inapposite" because "the case involved a mandamus petition." Opp., Dkt. 58 at 25, n.15. Yet, the § 706(1) standard is taken directly from the mandamus standard. *See Hells Canyon Pres. Council,* 593 F.3d. at 932 (applying the same standard as mandamus); *In re Cal. Power Exch. Corp.,* 245 F.3d at 1124 (taking precedent from case law under § 706(1)).

The unavailability of an unreasonable delay claim at this time does not mean that FDA can treat its April 29, 2021, determination as "tentative," or delay publishing an NPRM "indefinitely," nor does it mean that the agency's actions are "never subject to judicial review." *See* Opp., Dkt. 58 at 3, 19 (characterizing "defendants' views"). Defendants have made no such arguments. On the contrary, the opening brief acknowledged that, "in the unlikely event that an unreasonable amount of time passes between the next stages of the rulemaking process, Plaintiffs may bring another unreasonable delay

claim under § 706(1)." Dkt. 53 at 20, *citing Kempthorne*, 498 F. Supp. 2d at 297-98. But speculative and remote future claims do not save a case from dismissal on mootness, *Ctr. of Biological Diversity v. Lohn*, 511 F.3d 960, 964 (9th Cir. 2007), and the potential for a possible § 706(1) cause of action in the future does not mean Plaintiffs have stated a claim in this action now. As explained, Plaintiffs cannot state a claim for any relief beyond what FDA has already provided, and the Court should dismiss this case as moot and for failure to state a claim.

II. Plaintiffs' Additional Arguments Do Not Prevent Dismissal on Mootness.

A. The "Voluntary Cessation" Exception Does Not Apply to FDA's Actions.

Plaintiffs' reliance on the "voluntary cessation" exception to mootness is misplaced. That exception exists for cases in which a defendant has ceased unlawful conduct, but may resume it after the case is dismissed. *See Friends of the Earth, Inc., v. Laidlaw Env't Servs.*, 528 U.S. 167, 189-94 (2000) (applying the exception to a wastewater treatment plant that stopped illegal discharges in response to litigation, but could resume polluting at any time). That exception generally does not apply when a party sues to compel discrete agency action, because once the action is completed, it is no longer possible for that action to be withheld. *See, e.g.*, *Lohn*, 511 F.3d 960 at 965 (holding that "voluntary cessation" exception did not apply after action on an endangered species act petition was complete). Such is the case here. Plaintiffs describe the citizen petition response and statutory determination as if they were merely precatory policy statements. *See* 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 145 (comparing the citizen petition response to a former Commissioner's 2018 press release); *Barclays Bank Pub. Ltd. Corp. v. Franchise Tax Bd.*, 512 U.S. 298, 329-330 (1994) (stating that Executive Branch press releases are "precatory" statements that "lack the force of law."). However, the citizen petition response and determination are official agency decisions issued pursuant to statute and regulation, and now that they are completed, it is no longer possible for them to be withheld. Mot., Dkt. 53 at 5-6.

Plaintiffs' comparison of their present circumstances to those in *Rosemere* is unavailing. *See* Opp., Dkt. 58 at 17, *citing Rosemere Neighborhood Ass'n v. U.S. EPA,* 581 F.3d 1169, 1174 (9th Cir. 2009). In that case, the Rosemere Neighborhood Association filed a series of civil rights complaints under Title VI, and ultimately asked the court to compel EPA to investigate. *Rosemere*, 581 F.3d at 1171-73. EPA moved to dismiss on mootness after it concluded its investigation, arguing that Rosemere

had no more pending complaints. *Id.* at 1173. However, Rosemere argued that it intended to file future petitions, and thus that a declaratory judgment could affect the parties' future rights under Title VI, rendering it an active controversy. *Id*. That is a sharp contrast to this case, which has always involved a single citizen petition and determination on a specific tobacco product standard. Mot., Dkt. 53 at 3-4. The response to that citizen petition and determination are now in the past. A declaratory judgment from the Court will not change the date they were issued. *See Lohn*, 511 F.3d 960 at 964 (stating that once an agency has completed the requested action, a declaratory judgment about past practices "would serve no purpose.").

Plaintiffs also attempt to find a "pattern of delay by FDA" that resembles the "consistent pattern of delay" found in *Rosemere*. Opp. Dkt. 58 at 20, n. 12. But they have shown no such pattern. Plaintiffs located six cases finding unreasonable delay by FDA over the past thirty-seven years. Those cases cover different topics, including tampon warnings and livestock antibiotics, and different provisions of the Federal Food Drug and Cosmetic Act. *Id.* at 20-21. None of those cases involved tobacco products or the Tobacco Control Act, and nothing about those cases suggests the repetition of relevant conduct.

Finally, even though mootness in this case does not depend on any further action by Defendants, it is worth observing that "unlike in the case of a private party, [courts] presume the government is acting in good faith." *Am. Cargo Transp. Inc. v. United States*, 625 F.3d 1176, 1180 (9th Cir. 2010) (finding mootness on the basis of a policy change). Plaintiffs' statements overlook this presumption. For example, Plaintiffs accuse Defendants of actions "designed not to ensure full compliance with their legal obligations, but primarily to put an end to this litigation." Opp., Dkt. 58 at 18. The Ninth Circuit has rejected that argument. *See Am. Cargo Transp. Inc.,* 625 F.3d at 1180 (stating that an "effort to forestall mootness by characterizing the government's action as 'strategic mootness' does not save the day."). The government enjoys more solicitude than private parties, and it is presumed that governmental entities and officials will follow through with new policy announcements and are unlikely to resume any alleged unlawful conduct. *Am. Cargo Transp. Inc.,* 625 F.3d at 1179-80, following *inter alia Coral Springs St. Sys., Inc. v. City of Sunrise,* 371 F.3d 1320, 1328–29 (11th Cir. 2004).

B. Additional Evidence is Not Necessary to Establish Mootness as a Matter of Law.

In a final effort to avoid dismissal, Plaintiffs demand "evidence that FDA is now drafting the NPRM." Opp. Dkt. 58, at 12. Yet that agency action is already demonstrated in the memorandum from Acting Commissioner Janet Woodcock, directing the Center for Tobacco Products to "engage in the rulemaking process… [and] promptly draft a proposed rule."[3] No further evidence is needed to establish that government officials are executing the duties described in public records. *See Red Top Mercury Mines, Inc. v. United States*, 887 F.2d 198, 202–03 (9th Cir. 1989) ("There is a presumption of regularity in the performance of their duties by government officials."). Similarly, no additional evidence is needed to educate Plaintiffs on federal rulemaking—an established regulatory process with time-consuming legal requirements that are beyond any serious dispute. *See* Mot., Dkt. 53 at 8 (describing the process for drafting an NPRM).

Finally, it is axiomatic that the Court may consider public records cited in the complaint without accepting Plaintiffs' characterizations and conclusions. *See Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) ("We are not, however, required to accept as true allegations that contradict exhibits attached to the Complaint . . . or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences."). Here, Plaintiffs' claims were mooted by two simultaneous events—both well documented in the public records cited in the Second Amended Complaint (First Supplement)—the response to the citizen petition and FDA's determination that menthol should be added to the flavor ban. Mot., Dkt 53 at 5-6. Indeed, the mootness and legal sufficiency of Plaintiffs' claims does not depend on whether or not FDA is working on the proposed rule. The claims fail because Plaintiffs have already received the only legally-available relief, and no law requires that FDA issue a proposed rule simultaneously. Nothing more is needed to demonstrate mootness and failure to state a claim, and the Court should grant Defendants' motion.

CONCLUSION

For the foregoing reasons, Plaintiffs' claims should be dismissed without prejudice.

[3] Cited at 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 144 and Mot., Dkt. 53 at 6, n.3 and available in the citizen petition docket at https://www.regulations.gov/document /FDA-2013-P-0435-0107.

Respectfully submitted,

Dated: July 21, 2021

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on July 21, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Christopher K. Leung: chris@pollockcohen.com

There are no manual recipients. I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: July 21, 2021 /s/ Sarah Williams
SARAH WILLIAMS