SARAH WILLIAMS
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice, Civil Division
PO Box 386
Washington, DC 20044-0386
Telephone: 202-616-4269
Fax: 202-514-8742
sarah.williams@usdoj.gov

Counsel for Defendants

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 of the Center for Tobacco Products.

Defendants.

Case No. 4:20-cv-4012-KAW

FEDERAL DEFENDANTS' NOTICE OF MOTION, SECOND MOTION TO DISMISS AND MEMORANDUM IN SUPPORT

DATE: July 15, 2021
Time: 1:30pm
Judge: Hon. Kandis Westmore

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

FEDERAL RULES

FEDERAL REGULATIONS

OTHER AUTHORITIES

NOTICE OF MOTION

PLEASE TAKE NOTICE that on July 15, 2021 at 1:30 pm, in the United States Courthouse at Oakland, California, Defendants United States Department of Health and Human Services, Xavier Becerra, United States Food and Drug Administration, Dr. Janet Woodcock, Center for Tobacco Products, and Mitchell Zeller will move to dismiss this action.

MOTION TO DISMISS

Defendants hereby move to dismiss this action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) for the reasons set forth in the following Memorandum of Points and Authorities.

MEMORANDUM OF POINTS AND AUTHORITIES

PRELIMINARY STATEMENT

On June 17, 2020, Plaintiffs sued the United States Food and Drug Administration (FDA) and related Federal Defendants, seeking regulation of menthol as a characterizing flavor in cigarettes under the Family Smoking Prevention and Tobacco Control Act of 2009 (the Tobacco Control Act or the Act), which bans most flavors in cigarettes but expressly exempts menthol. Before any action by the Court, Defendants committed to responding by a date certain to a citizen petition submitted by Plaintiffs and other organizations, and moved to dismiss another claim on grounds that the Tobacco Control Act leaves the regulation of menthol to FDA's discretion. To survive that motion, Plaintiffs took the narrow position that the statute required only a determination as to whether existing tobacco product standards should be changed, and did not argue that the Tobacco Control Act required FDA to add menthol to the flavor ban. The Court then ruled that the statute "does not necessarily require that FDA modify the flavor ban, but a *determination* of whether the flavor ban should be modified is required by the statute." Order, Dkt. 34 at 8 (emphasis added) (further stating that "the Court does not suggest that the FDA must ban menthol").

On April 29, 2021, FDA resolved Plaintiffs' citizen petition by granting it. The response specifically included a determination under 21 U.S.C. § 387g(a)(5) that the flavor ban should be changed to include menthol. The Acting FDA Commissioner concurrently issued a memorandum implementing the grant by directing FDA's Center for Tobacco Products to engage in the rulemaking process by promptly beginning to draft the proposed rule. Those actions represent the only relief that Plaintiffs could achieve on an unreasonable delay claim under the Administrative Procedure Act (APA). Nevertheless, Plaintiffs wish to continue this case in an effort to oversee the agency's rulemaking process, but that is not a good use of judicial resources and not the role of the Court under the APA. Accordingly, the Government moves to dismiss for lack of subject matter jurisdiction and failure to state a claim.

STATEMENT OF THE ISSUES

1. Whether Plaintiffs' claims for unreasonable delay are moot after Defendants acted by providing all the relief to which Plaintiffs are legally entitled?
2. Whether Plaintiffs have failed to state a claim for unreasonable delay when no additional agency action can be compelled?

BACKGROUND

A. The Tobacco Control Act, Tobacco Product Standards, and Citizen Petitions

The Tobacco Control Act established a comprehensive scheme for regulating all tobacco products in the United States. Pub. L. No. 11-31, 123 Stat. 1776 (2009), *codified* at 21 U.S.C. § 387 *et. seq.* Tobacco product standards are one mechanism for regulating tobacco products under the Act. *See id.* at § 387g. The tobacco product standards enacted by Congress include a provision banning cigarettes with characterizing flavors other than tobacco and menthol, commonly known as the "flavor ban. *Id.* at § 387g(a)(1)(A). The Act also provides that the Secretary of Health and Human Services, acting through FDA, shall periodically evaluate the tobacco product standards "to determine whether such standards

should be changed to reflect new medical, scientific or other technological data." *Id*. at § 387g(a)(5). If FDA determines that a tobacco product standard should be changed, the change must be implemented by "notice and comment" rulemaking in accordance with the statute, the APA, and other applicable laws and Executive Orders that govern changes to federal regulations. *See generally*, 5 U.S.C. § 553 (Rulemaking); 21 U.S.C. § 387g(a)(2), (c) (Tobacco Product Standards); Executive Order 12,866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (October 4, 1993).

Interested members of the public can also request that FDA make changes to regulations, including the tobacco product standards, through the citizen petition process outlined in 21 C.F.R. § 10.30, which allows petitioners to submit a formal request for agency action and receive a response that either grants or denies the petition, in whole or in part, or grants "such other relief or take[s] other action as the petition warrants." *Id.* at § 10.30(e)(3); *see also* 5 U.S.C. § 553(e) (giving interested persons a right to petition for regulatory change). If FDA grants a request for rulemaking in a citizen petition, the agency employs the same, well-established "notice and comment" rulemaking process that applies when the agency decides to issue or amend a tobacco product standard.

B. The Original Complaint and First Motion to Dismiss

Plaintiffs' complaint has consistently contained two basic claims under the APA, 5 U.S.C. §§ 555 and 706(1), alleging unreasonable delay both in addressing menthol as a characterizing flavor in cigarettes (Claim I), and in responding to Plaintiffs' citizen petition (Claim II). *See* Compl. Dkt. 1, *and compare* 2d Am. Compl. (Supp.), Dkt. 52. Before any action by the Court, FDA committed to responding to the citizen petition by a date certain. JCMS, Dkt. 20 at 3. Defendants then moved to dismiss Claim I on grounds that the Tobacco Control Act did not require any specific action on menthol cigarettes, let alone a menthol ban, and instead explicitly exempted menthol from the flavor ban, leaving changes in tobacco product standards to FDA's discretion and subject matter expertise. Mot. to Dismiss, Dkt. 26. To survive that motion, Plaintiffs abandoned their allegations that FDA was required to ban

menthol and took a narrower position that the statute requires only a determination as to whether to add menthol to the flavor ban. *See* Opp., Dkt. 28 (failing to defend claims that the Tobacco Control Act requires a menthol ban); Reply, Dkt. 30 at 1-2 (noting the abandonment). Indeed, after that briefing, the Court's first question for Plaintiffs at the motion hearing was to clarify the relief they sought on Claim 1:

> THE COURT: Mr. Leung, what is it that the Plaintiffs are expecting? I got the impression from what I read that Plaintiffs were simply wanting the FDA to make a determination based on the information that it received. … And so is it that the Plaintiffs are arguing that there is a mandatory duty for the FDA to ban menthol cigarettes or to just make a determination about whether or not they should be banned or whether or not other regulations should be imposed?
>
> MR. LEUNG: Thank you, Your Honor. The Plaintiffs for Claim 1 are only asking that this Court require FDA to do what is required under the law, and that is to make a determination as to whether or not menthol should be added to the flavor ban list…. [A]t this particular stage we are only asking FDA to make a determination one way or the other as to whether or not menthol should be added to the flavor ban.

11/5/20 Tr., Dkt. 33 at 4:18-22; 5:7-15, 21-24.

Plaintiffs reiterated that position later in the hearing, stating:

> That all said, the purpose of Claim 1 is essentially to make FDA complete the latter half of what (a)(5) requires, which is basically a determination. FDA has not made such a determination. That is what we are trying to achieve through Claim 1.

Id. at 14:18-22.

In support of Claim 1, Plaintiffs relied on a provision in the Tobacco Control Act which states that FDA "shall provide for the periodic evaluation of tobacco product standards … to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." 21 U.S.C. § 387g(a)(5). That provision places no requirements on the form of the determination, thus leaving it entirely to FDA's discretion. *Id.* At the November 5, 2020 hearing, Plaintiffs agreed that 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. 33 at 9:15-19. Following that hearing, on November 12, 2020, the Court ruled that the Tobacco Control Act does not require FDA to modify the flavor ban, but does require FDA to "make a determination of whether to *modify* the

standard, which may include adding menthol cigarettes to the flavor ban." Order, Dkt. 34 at 4, 8 (emphasis in original). Consistent with the statute, the Court's Order did not specify what process or form the agency should use for its determination. *Id.*

C. FDA's Citizen Petition Response and Determination that Menthol Should be Added to the Flavor Ban

On April 29, 2021, FDA issued its final response to Plaintiffs' citizen petition and included in its response a determination that the existing tobacco product standard should be changed to eliminate menthol as a characterizing flavor in cigarettes. *FDA Citizen Petition Response*, Dkt. No. FDA-2013-P-0435, April 29, 2021 (C.P. Resp.) at 14.[1] That response reflected FDA's review of not only the original petition and numerous studies and literature it cited, but also the lengthy citizen petition supplement that Plaintiffs submitted on January 14, 2021, which included seventy-eight additional sources not cited in the original petition. *Id.* at 2, 9, 11 (responding to the January 14, 2021 citizen petition supplement).[2] The response also reflected FDA's review of thousands of comments submitted to the citizen petition docket, *id.* at 9-12 (summarizing the 2,060 comments received on the citizen petition), and the review of multi-year research projects supported by FDA and other Federal agencies, *id.* at 6-7 (citing, *inter alia*, peer-reviewed articles published in 2019, 2020 and 2021).

In its response, FDA granted Plaintiffs' citizen petition and stated that it interpreted the petition "as a request that the Agency engage in the rulemaking process by proposing a rule to prohibit menthol as a characterizing flavor in cigarettes." *Id.* at 2, 8 n. 26 (noting that the agency's interpretation was necessary in part because the citizen petition did not follow the regulations for describing requested action in 21 C.F.R. § 10.30(b)(3)). To grant the request, FDA stated that it would engage in the

[1] *Letter from May D. Nelson. Director, Office of Regulations, Center for Tobacco Products, FDA, to D. Douglas Blanke, J.D., Public Health Law Center, available at* https://www.regulations.gov/document/FDA-2013-P-0435-0106, and previously filed with this Court at Dkt. 50-1 (Second JCMS, Attach. A) and cited by the Second Amended Complaint (First Supplement), Dkt. 52 at ¶¶ 140, 141, 160 and 168.

[2] The January 14, 2021 citizen petition supplement is cited by the Second Amended Complaint (First Supplement), Dkt. 52 at ¶ 139, n. 61.

established process of notice-and-comment rulemaking to issue a rule proposing to add menthol to the flavor ban. *Id.* at 2, 14.

The Acting FDA Commissioner concurrently took appropriate action to implement the approval of the citizen petition by "directing the Center for Tobacco Products to engage in the rulemaking process by promptly beginning to draft the proposed rule." April 29, 2021, Memorandum from Acting Commissioner of Food and Drugs Janet Woodcock to Mitch Zeller, Director, Center for Tobacco Products, Implementing Approval of Citizen Petition regarding Banning Menthol as a Characterizing Flavor in Cigarettes under Section 907 of the Federal Food, Drug and Cosmetic Act (Implementation Memo);[3] *see also* 21 C.F.R. § 10.30(e)(2)(i) (when approving a citizen petition, "the Commissioner shall concurrently take appropriate action … implementing the approval"). At the same time, FDA publicly announced the upcoming regulation and its intent to publish a notice of proposed rulemaking (NPRM) in the Federal Register within the next twelve months. *See* FDA Press Announcement, April 29, 2021 Statement (2021 FDA Announcement).[4] Observing that the NPRM "will involve important public health issues," FDA stated that it is "highly committed" to issuing the NPRM to eliminate menthol as a characterizing flavor in cigarettes, and that the proposed rule will be "one of the Agency's highest priorities." C.P. Resp. at 14.

D. The Regulatory Process for Adding Menthol to the Flavor Ban

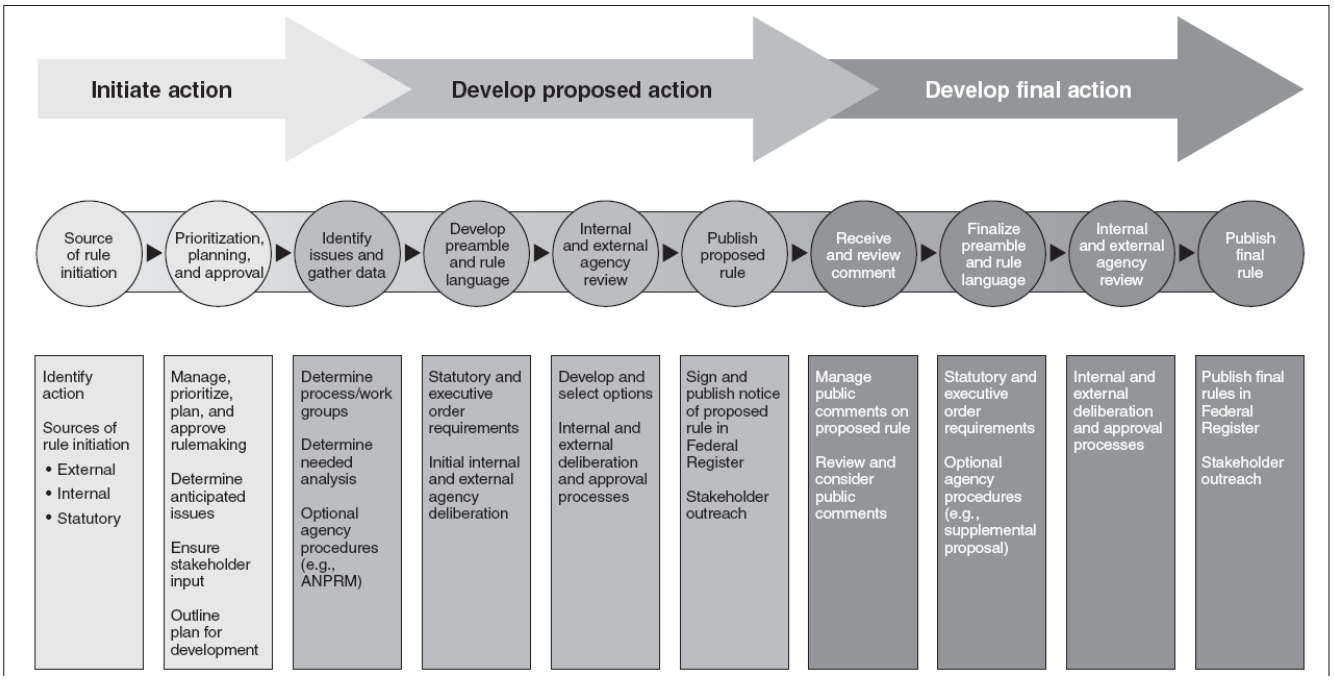
Plaintiffs' submissions mistakenly assume that the rulemaking process requires only three steps set forth in the APA, beginning with the publication of an NPRM in the Federal Register, 5 U.S.C. § 553(b), *see* 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 161, 168. The reality is far more complex, with the

[3] Available in the citizen petition docket at: https://www.regulations.gov/document/FDA-2013-P-0435-0107, and cited by the Second Amended Complaint (First Supplement) at ¶ 144.

[4] *FDA News Release: FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers*, (April 29, 2021) *available at* https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers and cited by the Second Amended Complaint (First Supplement) at ¶ 141.

publication of an NPRM occurring in the middle—not the beginning—of the rulemaking process. The Government Accountability Office (GAO) provides a high level overview of the rulemaking process with three basic phases—"initiation of rulemaking actions, developing proposed rules, and developing final rules"—and their intermediary steps:

Figure 1: Basic Phases of Rulemaking Processes



Government Accountability Office, GAO-09-205, *Federal Rulemaking* 11-12 (2009) (*GAO Federal Rulemaking*).[5]

In the context of changing the flavor ban, FDA has entered the second phase of the rulemaking process, "develop proposed action," and is now drafting the NPRM. *See* C.P. Resp. at 14 (determining that the existing tobacco product standard should be changed); Implementation Memo (directing the Center for Tobacco Products to "promptly begin to draft the proposed rule"). The Tobacco Control Act does not set a timeline for NPRM publication, but FDA expects to issue the NPRM within twelve

[5] Available at https://www.gao.gov/products/gao-09-205. For a similar categorization and even more detailed discussion of the stages of rulemaking, *see also* Cornelius M. Kerwin & Scott R. Furlong. *Rulemaking: How Government Agencies Write Law and Make Policy* 68-76 (5th ed. 2018), http://search.ebscohost.com/login.aspx?direct=true&db=nlebk&AN=2685413&site=ehost-live.

months. *See* 21 U.S.C. § 387g(c)(1)(3) (proposed rule publication); 2021 FDA Announcement (FDA's expectation).

This second phase of rulemaking—developing the proposed action by drafting the NPRM—is time consuming and resource-intensive. It involves not only determining the text for the proposed regulation, but also explaining the support for it. GAO, *Federal Rulemaking* 19. That process requires contributions from a diverse staff, including writers, science and medical staff, regulatory counsel, attorneys, and economists. *Id.* During the drafting process, FDA must prepare a preamble for the proposed rule that fully explains the basis and evidentiary support for the regulation, 21 C.F.R. § 10.40(b)(1)(vii); complete related analyses, such as an analysis of economic impacts, *see* Executive Order 12,866 ("Regulatory Planning and Review"), OMB Circular A-4 ("Regulatory Analysis") (2003), and an environmental impact assessment, 21 C.F.R. § 10.40(b)(1)(ix); ensure that the scientific evidence on which the rule relies complies with the Information Quality Act, *see* 44 U.S.C. § 3516 *et seq.*; and make certain that important factual material is disclosed, *see Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 239 (D.C. Cir. 2008).

Once drafted, the NPRM may be deemed "significant" pursuant to Executive Order 12,866, and accordingly, may be submitted to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB), which reviews rules on OMB's schedule and circulates them for interagency review. *See* GAO, *Federal Rulemaking* at Figure 1, *supra* (discussing internal and external approval processes before publication); *and* C.P. Resp. at 14 (anticipating "input from other agencies and departments across the Government during the rulemaking process"). After these reviews, FDA submits the NPRM to the Office of the Federal Register for publication, beginning the public comment period and the third phase of the rulemaking process. *See* 5 U.S.C. § 553(b); 21 C.F.R. § 10.40 (b)(1) (Promulgation of Regulations); GAO, *Federal Rulemaking* at Figure 1, *supra.* As discussed, FDA is working expeditiously to complete the second phase of the rulemaking process and expects to publish

an NPRM within the next twelve months. *See* 2021 Announcement; C.P. Resp. at 14 (stating the agency's commitment to the NPRM).

E. The Second Amended Complaint (First Supplement) and Second Motion to Dismiss

As a result of FDA's actions, Plaintiffs obtained both a determination under 21 U.S.C. § 387g(a)(5) and a final response to their citizen petition. *See* C.P. Resp. at 14. Plaintiffs also obtained the rulemaking action they sought and continue to seek as relief; FDA is now actively engaged in the rulemaking process to add menthol to the flavor ban. *Id.* at 14; 2d Am. Compl. (Supp.), Dkt. 52, at 51 ¶ 3 (requesting an order "directing Defendants to begin the rulemaking process"). Nevertheless, rather than stipulating to dismissal, Plaintiffs supplemented their Second Amended Complaint urging the Court to oversee FDA's rulemaking process. 2d A. Compl. (Supp,), Dkt. 52, at ¶ 18. To justify continued judicial involvement, Plaintiffs attempt to create a controversy where none exists by asserting, incorrectly, that FDA "declined to begin rulemaking," and that the determination under § 387g(a)(5) and citizen petition response remain unreasonably delayed until a "notice" is published in the Federal Register. *Id*. 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 161, p. 50-51. The Government now moves to dismiss Plaintiffs' claims as moot under Rule 12(b)(1), and for failure to state a claim upon which relief could be granted under Rule 12(b)(6).

LEGAL STANDARD

Mootness is "a jurisdictional question because the Court is not empowered to decide moot questions or abstract propositions." *North Carolina v. Rice*, 404 U.S. 244, 246 (1971) (quoting *United States v. Alaska S.S. Co.,* 253 U.S. 113 (1920), and explaining that the requirement derives from Constitutional limits on courts' Article III powers). The mootness doctrine is related to standing, as it restricts judicial power to active cases and controversies, and reserves the general policy-making power for the elected branches of government. *Nome Eskimo Comm. v. Babbitt*, 67 F.3d 813, 815 (9th Cir. 1995), *citing Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559-61 (1992). The defendant bears the

burden of establishing mootness. *Feldman v. Bomar,* 518 F.3d 637*,* 642 (9th Cir. 2008). Once mootness is established, the case must be dismissed. *Id.* at 644.

Because mootness is jurisdictional, dismissal is appropriate under Rule 12(b)(1) for lack of subject matter jurisdiction, rather than under Rule 12(b)(6) for failure to state a claim. Apart from mootness, however, dismissal of Plaintiffs' additional demands for relief is also appropriate under Rule 12(b)(6). Specifically, Plaintiffs fail to identify any additional agency action that the Court could compel under § 706(1), and therefore fail to state a claim upon which relief could be granted. Both rules apply the same standards for facial attacks on a complaint—the inquiry does not involve facts outside the complaint, but instead focuses on the legal sufficiency of the claims. *See Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). Accordingly, the court assumes that factual allegations are true, but "mere conclusions [are] not entitled to the assumption of truth." *Id.*; *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (holding that the reviewing court must "determine whether [the allegations] plausibly give rise to an entitlement to relief").

ARGUMENT

A. Plaintiffs' Claims are Moot.

Mootness limits judicial power to cases in which the alleged wrong can be redressed by the lawsuit, and thus cases become moot when it is impossible for the court to grant any effective relief. *Chafin v. Chafin*, 568 U.S. 165, 172 (2013). Accordingly, available relief is critical to any mootness inquiry, and "the basic question in determining mootness is whether there is a present controversy as to which effective relief can be granted." *Feldman v. Bomar,* 518 F.3d 637, 642 (9th Cir. 2008). Under the APA, the only relief for an unreasonable delay claim is compelling the action that was unreasonably delayed. *See* 5 U.S.C. § 706(1) (providing a cause of action to "compel agency action unlawfully withheld or unreasonably delayed"); *S. Utah Wilderness Alliance v. Norton,* 542 U.S. 55, 65 (2004) (*SUWA*) ("A court can compel the agency to act, but has no power to specify what the action must be.")

Moreover, once the agency has acted, the unreasonable delay claim is moot and any claim for declaratory relief over that claim is correspondingly moot. *People for the Ethical Treatment of Animals v. U.S. Fish and Wildlife Serv.*, 59 F. Supp. 3d 91, 96 (D.D.C. 2014).

1. Plaintiffs Have Received All Legally-Available Relief on Their Claims.

Despite the changed factual circumstances since the commencement of the lawsuit, Plaintiffs have not altered their requests for relief. They still seek an order requiring FDA to "begin the rulemaking process," respond to the citizen petition, and make a determination under 21 U.S.C. § 387g(a)(5). *See* 2d Am. Compl. (Supp.), Dkt. 52, at p. 50-51; Compl. Dkt. 1 at p. 44. Additionally, Plaintiffs have not altered their request that FDA be ordered to undergo rulemaking to add menthol to the flavor ban. *See* 2d. Am. Compl. (Supp.), Dkt. 52 at Part IV (describing "FDA's unlawful refusal ban menthol") *and* JCMS, Dkt. 30 at 2 (stating that "Plaintiffs' request for rulemaking is still very much alive—not abandoned"); *but see also* Order, Dkt. 34 at 8 (no menthol ban was required).

On April 29, 2021, FDA responded to the citizen petition and made a determination under § 387g(a)(5) that the existing tobacco product standard should be changed to ban menthol. *See* C.P. Resp. at 14. That is all the relief that the Court could grant on Plaintiffs' unreasonable delay claims. *See SUWA*, 542 U.S. at 65 (stating that the court cannot specify the agency action). In addition, FDA granted the citizen petition's request for rulemaking and is actively engaged in the rulemaking process. Even if Plaintiffs were dissatisfied with the results, there is no further relief available to them on their unreasonable delay claims. *See Kuuzova v. U.S. Dept. of Homeland Sec.,* 686 Fed. App'x 506, 508 (9th Cir. 2017) (unpublished) (affirming dismissal of an APA unreasonable delay claim for mootness even though plaintiffs requested different action from the agency).

Indeed, courts have repeatedly dismissed unreasonable delay claims on mootness grounds even when Plaintiffs are not fully satisfied with the results of the agency's action. In addition to *Kuuzova,* multiple district court cases stand for the same proposition that agency action moots an unreasonable

delay claim regarding that action. For example, in *Western Radio Serv. v. U.S. Forest Serv.,* although the Forest Service only partially granted an application for antenna use, the decision rendered the entire claim for unreasonable delay on the application moot because the court had no power to compel a different action. Civ. No, 04-1346-AA, 2008 WL 427787 at *5 (D. Or., Feb. 12, 2008). Additionally, in *Schirripa v. Gottlieb*, the court dismissed an unreasonable delay claim regarding a citizen petition response, holding that the claim could not survive a motion to dismiss on mootness after the agency had responded to the petition. Civ. No. 17-cv-1060, 2018 WL 4567163 at *1 (D.D.C., Sept. 24, 2018) *aff'd Schirripa v. Sharpless,* No. 18-5329, 2019 WL 3229439 at * 1 (D.C. Cir. 2019) (unpublished) ("Appellant's complaint was properly dismissed as moot because Appellant obtained the mandamus relief he sought when Appellee responded to his administrative petition."). Similarly, in *Friends of Animals v. Pruitt*, an agency denied a rulemaking petition to protect wild horses, rendering the unreasonable delay claim on the petition incurably moot. 258 F. Supp. 3d 91, 94 (D.D.C. 2017). And again, in *Burk v. FDA*, FDA denied the plaintiff's citizen petition after the lawsuit was filed, providing the only legally-available relief on plaintiff's claim and thus rendering it moot. Civ. No. 19-73, 2019 WL 2010195 at *1-*2 (D. Md., May 6, 2019) ("Where the relief sought by a party has been provided, there is no longer a case or controversy involved.").

The decision in *Center for Biological Diversity v. Kempthorne*, 498 F. Supp. 2d 293 (D.D.C. 2007), is particularly instructive. There, the Center for Biological Diversity sued the Fish and Wildlife Service for unreasonable delay in responding to a citizen petition that sought rulemaking to protect the Mexican gray wolf. *Id.* at 293-94 (D.D.C. 2007). As in this case, the agency granted the petition for rulemaking during the litigation and then moved to dismiss on mootness grounds. *Id.* The citizen petition response asserted that the agency had started the process of changing the existing regulations to protect the gray wolf. *Id.* at 295. Like Plaintiffs here, the Center did not allege that the response was unlawful under § 706(2), but instead maintained its unreasonable delay claim, arguing that the litigation

should continue through the rulemaking process to ensure the Center's requested changes to the regulation were implemented. *Id.* at 297. The court disagreed and dismissed, holding that the Center could not overcome mootness of its unreasonable delay claim by anticipating future delays in the regulatory process. *Id.*

The Court should reach the same result here because there is no need for, and thus no effective relief, in an order requiring Defendants to do what they have already done: "begin the rulemaking process for adding menthol to the list of characterizing flavors banned by the Tobacco Control Act," "respond to the Citizen Petition submitted by plaintiff African American Tobacco Control Leadership Council et. al.," and "undertake and complete an evaluation of tobacco product standards to determine whether such standards should be changed to reflect new medical, scientific or other technological data." *See* 2d Am. Compl. (Supp.) at 50-51; *Natural Res. Def. Council Inc. v. Nuclear Regulatory Comm'n*, 680 F.2d 810, 814-15 (D.C. Cir. 1982) (finding a case moot, because even if the argument was originally well-founded, the court could "hardly order [the agency] at this point to do something that it has already done"). In short, Plaintiffs have now received all the requested relief to which they are legally entitled, and there is no remaining controversy between the parties upon which effective relief could be granted. *See McBryde v. Comm. to Review Circuit Council Conduct and Disability Orders of the Judicial Conference of the United States,* 264 F.3d 52, 55 (D.C. Cir. 2001) ("If events overrun the controversy such that the court cannot grant meaningful relief, the case must be dismissed as moot."). The case should therefore be dismissed as moot.

2. Plaintiffs' Additional Demands Regarding Publication in the Federal Register Cannot Lead to Plausible Relief, and Thus Do Not Prevent Dismissal on Mootness.

In spite of receiving the only legally-available relief on both of their unreasonable delay claims—a determination under 21 U.S.C. § 387g(a)(5) and a response to the citizen petition—Plaintiffs seek to maintain these claims by challenging FDA's progress and timeline for the proposed menthol

rule. *See* 2d Am. Compl. (Supp.) at ¶ 18 (seeking continued "judicial oversight and intervention"). To that end, Plaintiffs attempt to manufacture controversies where none exist, attaching a special significance to publication of a "notice" in the Federal Register, *see* 2d Am. Compl. (Supp.), Dkt. 52 at 51 ¶ 5, and further alleging FDA is required to publish a notice of proposed rulemaking in order to: (1) make a determination under 21 U.S.C. § 387g(a)(5); and (2) comply with the requirement of 21 C.F.R. § 10.30(e)(2)(i) to take "appropriate action" implementing the citizen petition approval. *See id.* at ¶¶ 143-44, 168 (alleging that Defendants did not take appropriate implementing action and specifying that "appropriate action is "proposing a rule in the Federal Register"), ¶ 155 (alleging that Defendants' determination under 21 U.S.C. § 387g(a)(5) is "inadequate" because it was "unaccompanied by action"). Yet Plaintiffs' additional demand for relief in the form of publication in the Federal Register (whether for proposed rulemaking or something else) lacks a basis in the Tobacco Control Act and the regulations, is inconsistent with Plaintiffs' past representations to the Court, and demonstrates a misunderstanding of the rulemaking process. In short, Plaintiffs' additional demands do not raise any plausible relief that the Court could legally grant under the APA. *See Chafin*, 568 U.S. at 174 (stating that claims should be dismissed when they are so implausible that they are insufficient to preserve jurisdiction).

a. The Tobacco Control Act Does Not Require That a Determination Under § 387g(a)(5) Take the Form of a Notice in the Federal Register.

Plaintiffs allege that the determination whether to change a tobacco product standard cannot be made under 21 U.S.C. § 387g(a)(5) without publication of a notice in the Federal Register, 2d Am. Compl. (Supp.), at ¶ 155, p. 51 (Requested Relief #5). Plaintiffs' argument is implausible. At the outset, this allegation contradicts Plaintiffs' position at the November 5, 2020 motion hearing, where counsel stated that "of course" the determination under 21 U.S.C. § 387g(a)(5) could take the form of the Government's choice. 11/5/20 Tr., Dkt. 33 at 9:15-19; *see United States v. Georgia-Pacific Co.*, 421 F.2d 92, 96, (9th Cir. 1970) ("a party [cannot] assum[e] inconsistent positions to the detriment of another party."). In fact, Plaintiffs' counsel listed several options for the form of the determination, including an

email, a letter to Plaintiffs, or in the response to a citizen petition, the latter of which is exactly where FDA set forth its determination here. *Id.*

Moreover, Plaintiffs' allegation is not based on a plausible interpretation of the Tobacco Control Act. As described *supra* in the Background, Parts A and D, 21 U.S.C. § 387g(a)(1)(A) established the flavor ban, which prohibits certain "characterizing flavor[s]" for "tobacco product[s] or tobacco smoke." Plaintiffs' citizen petition requested that FDA revise the *existing* flavor ban to include menthol. C.P. Resp. at 1. The Tobacco Control Act permits FDA to "revise the tobacco product standards in paragraph (1)"—which include the flavor ban in paragraph (1)(A)—"in accordance with subsection (c)." 21 U.S.C. § 387g(a)(2); *see* C.P. Resp. at 14 (stating that § 387g(c) applies). Section 387g(c), in turn, describes the notice-and-comment rulemaking process that FDA follows when amending a tobacco product standard. But neither of these provisions concern what is at issue here, FDA's *determination* to add menthol to the flavor ban, and the provision that governs such determinations, 21 U.S.C. § 387g(a)(5), imposes no requirement that they be made in or be accompanied by a notice in the Federal Register.

Plaintiffs nonetheless allege that FDA's determination was "inadequate" and demand that the Court order "publication in the Federal Register." *See* 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 155, p. 51 (Requested Relief #5). However, none of the Tobacco Control Act provisions cited by Plaintiffs support their demand. Plaintiffs point to 21 U.S.C. § 387g(a)(3)(B)(ii), *see* 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 155, but § 387g(a)(3), by its own terms, only applies to *new* "tobacco product standards" that are adopted "*in addition to* those in paragraph (1)," 21 U.S.C. § 387g(a)(3)(A) (emphasis added). And FDA intends (as Plaintiffs petitioned) to amend the *existing* flavor ban established in "paragraph (1)"—*i.e.*, 21 U.S.C. § 387g(a)(1)—to include menthol. C.P. Resp. at 2, 14. Thus, § 387g(a)(3) and its subparagraphs are simply inapplicable. Moreover, even if § 387g(a)(3)(B)(ii) applied (it does not), that provision does not require FDA to publish anything in the Federal Register. Rather, it simply permits "any party

objecting" to a proposed new tobacco product standard to provide certain "scientific evidence" for the agency's consideration after the NPRM has been published. 21 U.S.C. § 387g(a)(3)(B)(ii).

Plaintiffs' attempted reliance on 21 U.S.C. § 387g(a)(2) and (c) is similarly misplaced. *See* 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 155. As explained above, those provisions merely require FDA to use notice-and-comment rulemaking when revising an existing tobacco product standard, a process FDA intends to follow to add menthol to the flavor ban. C.P. Resp. at 2, 14. Neither provision imposes timing requirements for FDA to issue an NPRM, much less commands the issuance of a Federal Register notice when FDA determines, under 21 U.S.C. § 387g(a)(5), that an existing tobacco product standard should be changed. And the Tobacco Control Act may not be altered through this litigation to "add[] terms not found in the statute" or "impos[e] limits on [the] agency's discretion that are not supported by the text." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2381 (2020). Accordingly, Plaintiffs have failed to plausibly allege any additional action under the Tobacco Control Act that FDA is legally required to take.

b. FDA's Regulation Does Not Require That a Citizen Petition Approval be Implemented by Publication of a Notice in the Federal Register.

Plaintiffs also allege that citizen petitions cannot be granted 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 under 21 C.F.R. § 10.30(e)(2)(i). *See* 2d Am. Compl. (Supp.), Dkt. 52 at ¶¶ 144, 168. Notably, Plaintiffs are not challenging FDA's approval of the citizen petition or the process through which it was reached—they do not, for example, claim that the approval or the reasons underlying it were contrary to law under § 706(2)—but instead allege that FDA took a different implementing action than they would prefer, by issuing an implementation memorandum rather than publishing a notice in the Federal Register. *Compare id.* (alleging that FDA did not take "appropriate action") *with SUWA*, 542 U.S. at 65 (stating that the court cannot specify how the agency must act in an unreasonable delay case). In short, Plaintiffs' new claim for a specific implementing action under the

regulation is an entirely new invention that was not demanded in any previous versions of the complaint. *See, e.g.*, 1st Am. Compl., Dkt. 19 at ¶ 148 (citing a decision that required only a "written notice of decision accompanied by an explanatory statement" in response to the citizen petition).

Moreover, Plaintiffs' new demand is not based on a plausible interpretation of the underlying regulation. Section 10.30(e)(2)(i), which governs the approval of citizen petitions, provides only that the FDA Commissioner must "concurrently take appropriate action … implementing the approval." 21 C.F.R. § 10.30(e)(2)(i). The regulation does not constrain FDA's discretion regarding what type of concurrent implementing action is "appropriate," and indeed, it only sets out "(e.g., publication of a Federal Register notice)" in parentheses as an example of one *possible* "appropriate action." *Id.* But the language in parentheses does not make notice in the Federal Register the agency's *only* choice of implementing action, nor does it undercut the related regulatory provision that gives FDA discretion "to grant or deny such a petition, in whole or in part," or "grant such other relief or take other action as the petition warrants." *Id.* at § 10.30(e)(3). Where "the meaning of the regulation is clear, the regulation is enforced according to its plain meaning." *Minnick v. Commissioner*, 796 F.3d 1156, 1159 (9th Cir. 2015). Here, it is clear that the regulation does not require publication of a notice in the Federal Register as the implementing action for a citizen petition approval.

Even if there were any doubt that the use of "e.g." signals merely an example as opposed to a requirement, FDA indicated when it adopted the language that now appears in § 10.30(e)(2)(i) that the "e.g." phrase was *not* a requirement—"The [citizen petition] response shall be either (1) approval, accompanied by *some form of* implementing action, e.g., the publication of a notice of proposed rule making . . .." *Administrative Function, Practices, and Procedures*, 42 Fed. Reg. 4680, 4685 (Jan. 25, 1977) (emphasis added). Moreover, in *Biovail Corporation v. FDA*, 448 F. Supp. 2d 154 (D.D.C. 2006), the court rejected an argument that a similar "e.g." phrase in § 10.30(e)(2)(iii) reflects a requirement. That subsection provides, in part, that a tentative response to a citizen petition will "indicat[e] why the

agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information." The plaintiff argued that the examples in the regulation were required to be included in a petition response. *Biovail Corp.*, 448 F. Supp. 2d 154, 161-62. But the court disagreed, holding that "[a]lthough the regulation indicates examples, it does not indicate that the FDA's reasoning must be of a certain degree of detail," and that the regulation only specifies that the response indicate "why [FDA] has been unable to reach a decision." *Id.* Plaintiffs' virtually identical argument here should likewise be rejected as an attempt "to tinker with [the language of the regulation] by transmuting its meaning into something it does not say." *Id.* at 462.

B. Plaintiffs Cannot State a Claim for Unreasonable Delay Based on their Additional Demands for Relief or FDA's April 29, 2021 Citizen Petition Response.

Apart from mootness, Plaintiffs' complaint does not state a claim upon which relief could be granted under Rule 12(b)(6). Plaintiffs have failed to identify any additional action that can be compelled under § 706(1), and the April 29, 2021 citizen petition response cannot be the basis for an unreasonable delay claim. *See Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 933 (9th Cir. 2010) (affirming dismissal for failure to state a claim when plaintiffs could not identify any action the agency was legally required to take); *Kripke v. FDA,* 73 Fed App'x 486 (9th Cir. 2018) (unpublished) (affirming dismissal of an unreasonable delay claim under Rule 12(b)(6) when the claim was asserted prematurely after only a few months had passed).

With respect to Plaintiffs' additional demand for a notice in the Federal Register, as discussed *supra* in Part V.A.2, there is no legal requirement that FDA publish such notice at this stage in the rulemaking process. Accordingly, the publication of a notice is not a legally required action that can be compelled under § 706(1). *See SUWA*, 542 U.S. at 63 (holding that unreasonable delay claims are "limited to enforcement of a specific, unequivocal command, the ordering of a precise, definite act … about which the official has no discretion whatsoever."); *Hells Canyon Pres. Council,* 593 F.3d at 938 (stating that the agency's obligation must be so clearly set forth as to justify a writ of mandamus).

Plaintiffs have therefore failed to state a claim for unreasonable delay upon which relief could be granted.

To the extent Plaintiffs allege that FDA has unreasonably delayed publishing an NPRM as of the date FDA issued its citizen petition response, 2d Am. Compl. (Supp.), Dkt. 52 at ¶ 48, that argument likewise lacks merit. Before FDA issued its response on April 29, 2021, this Court held that FDA was not required under the Tobacco Control Act to modify the flavor ban. *See* Order, Dkt. 34 at 8 (holding that the Tobacco Control Act does not require a menthol ban). The agency thus had no obligation at that point to issue an NPRM in furtherance of the menthol ban. *See In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992) (holding that an unreasonable delay claim cannot begin before the agency's duty to act). FDA determined on April 29, 2021 that the existing tobacco product standard should be changed to eliminate menthol as a characterizing flavor in cigarettes, *see* C.P. Resp. at 14, and FDA is now engaged in notice-and-comment rulemaking on that subject and is developing an NPRM. Plaintiffs filed their second amended complaint (first supplement) twenty-two days after FDA responded to the petition. *See* Dkt. 52 (filed May 21, 2021). There is no plausible argument that FDA has unreasonably delayed any required action in the twenty-two days between its decision to grant the citizen petition and Plaintiffs' filing of a supplemented complaint. *See In re Cal Power Exch. Corp*., 245 F.3d 1110, 1125 (9th Cir. 2001) ("The cases in which courts have afforded relief [for unreasonable delay] have involved delays of years, not months."); *Kripke*, 730 Fed. App'x 486 (affirming dismissal for failure to state a § 706(1) claim when only seven months had passed).

Moreover, FDA's commitment in its April 29, 2021 citizen petition response to issue a proposed rule does not provide a basis for the Court to oversee the agency's rulemaking process. Courts generally do not manage the complex and time-intensive regulatory process, and doing so would be an unnecessary demand on judicial resources. *See Hells Canyon Pres. Council v. Richmond,* 841 F. Supp. 1039, 1044 (D. Or. 1993) (noting that courts avoid premature involvement in agency decision-making to

"conserve scarce judicial resources"); *see also Baker v. Director, U.S. Parole Com'n*, 926 F.2d 725 (9th Cir. 1990) (holding that courts should consider the practical and efficient use of judicial resources when dismissing cases under Rule 12(b)(6)). Additionally, contrary to Plaintiffs' insistence on "judicial oversight and intervention," 2d Am. Compl. (Supp.), Dkt 52 at ¶ 18, the APA is not intended to supplant the agency's role in directing the regulatory process. Rather, courts should "protect agencies from undue judicial interference with their lawful discretion," *SUWA*, 542 U.S. at 55-56, and "not intrude on the agency's turf and thereby meddle in the agency's ongoing deliberations." *San Francisco Herring Ass'n v. USDOI*, 946 F.3d 564, 578 (9th Cir. 2019) (explaining the APA's requirement for final agency action and noting that litigation should not "prematurely insert courts into the mix").

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). *See Ctr. for Biological Diversity*, 498 F. Supp. 2d at 297-98 (noting that dismissal for mootness "does not prevent plaintiff from filing a new claim alleging unreasonable delay if defendants do not complete the rulemaking process… within a reasonable period of time"). In the meantime, FDA will continue to expeditiously prepare this complex public health rule consistent with the established notice-and-comment rulemaking process for changes to tobacco product standards.

CONCLUSION

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

Respectfully submitted,

Dated: June 9, 2021

BRIAN M. BOYNTON
Acting Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director

HILARY K. PERKINS
Assistant Director

/s/ Sarah Williams
SARAH WILLIAMS
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044-0386
Telephone: 202-616-4269
Fax: 202-514-8742
sarah.williams@usdoj.gov

Of Counsel:

DANIEL J. BARRY
Acting General Counsel
Department of Health and Human Services

MARK RAZA
Acting Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel, Litigation

SUSAN WILLIAMS
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Avenue
White Oak 32, Room 4520
Silver Spring, MD 20993-0002

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on June 9, 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: June 9, 2021 /s/ Sarah Williams
SARAH WILLIAMS