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UNITED STATES DISTRICT COURT

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,

vs.

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 the U.S. Food and Drug Administration; CENTER FOR TOBACCO PRODUCTS; MITCH ZELLER in his official capacity as the Center for Tobacco Products, Director,

Defendants.

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

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' SECOND MOTION TO DISMISS

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Plaintiffs African American Tobacco Control Leadership Council, Action on Smoking and Health, the American Medical Association, and the National Medical Association submit this brief in opposition to defendants' second motion to dismiss.

PRELIMINARY STATEMENT

Over a decade ago, Congress passed the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). The Act banned all flavors in tobacco products except menthol. However, Congress made clear that it was urgently concerned about the harmful effects of menthol in cigarettes, and especially concerned about proportionately higher rates of menthol cigarette use among African American smokers. The Act directed defendants to take a number of specific steps to gather information concerning menthol, and then to make a determination of whether the flavor ban should be updated to include it. *See* Order Granting in Part and Denying in Part Motion to Dismiss (ECF No. 34) ("MTD Order").

Defendants spent the next ten years collecting information showing that banning menthol would benefit public health. This included a wealth of evidence contained in Plaintiff African American Tobacco Control's citizen petition seeking a menthol ban, which was submitted in 2013 and supplemented in 2021. Former FDA Commissioner Scott Gottlieb even made public statements in 2018 that FDA intended to ban menthol in tobacco products and would soon be promulgating a proposed rule to that effect. Instead, defendants took no action on menthol and no action on the citizen petition.

Finally, in June 2020, plaintiffs initiated this litigation to compel defendants to cease their unlawful delay and comply with their statutory obligations with respect to the citizen petition and menthol more generally. Among other things, the complaint asked the Court to order defendants to make the initial determination of whether to add menthol to the flavor ban, and to begin the rulemaking process to effectuate that change. Defendants agreed (post-filing) to respond to the citizen petition, but argued that the other counts should be dismissed because the court lacked jurisdiction to order them to make any determination with respect to menthol. The Court rejected this argument, holding that "a determination of whether the flavor ban should be

modified is required by the statute." MTD Order at 8. Defendants then claimed that they would provide the required determination together with their anticipated citizen petition response.

On April 21, 2021, defendants provided the long-awaited citizen petition response and determination. On a positive note, the response reached the correct conclusion based on the relevant evidence—defendants stated that they would update the flavor ban to include menthol. Unfortunately, defendants appear to believe (incorrectly) that a statement of intent satisfies their obligations under the Tobacco Control Act and the citizen petition regulations. Thus, the citizen petition response and purported "determination" were not accompanied by any formal rulemaking action that would implement defendants' stated intent to ban menthol.

Defendants acknowledge that the rulemaking process is the mechanism through which defendants must implement the menthol ban, but claim to have satisfied all of their legal obligations just by saying that they would be starting this process. This is fundamentally illogical. It is also inconsistent with the language of the Act and the regulations. For example, in discussing a determination to ban additives in tobacco products, the Act references "a determination, set forth in a proposed tobacco product standard in a proposed rule." 21 U.S.C. § 387g(a)(3)(b)(ii). Similarly, the regulation governing citizen petitions require that when a petition is approved "the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval." 21 C.F.R. § 10.30(e)(2)(i).

Defendants attempt to confuse the issue with statements that a response or determination could take different forms. That is true, especially if the response or determination is that the agency will simply maintain the status quo and take no action. But it does not follow that when the agency has made a statutorily required determination or approved a citizen petition request the agency has no obligations to take appropriate action to effectuate those decisions.

The response also made clear that defendants' cavalier defiance of the Congressional mandate to act quickly on menthol had not been corrected—even after this Court specifically rejected defendants' arguments that the Tobacco Control Act allowed endless evaluation of menthol. The response asserted that FDA could still take any action or no action on menthol, on

a schedule of its choosing. Worse, FDA stated that it expected to take an entire year (or more) to issue a notice of proposed rulemaking ("NPRM"). The NPRM is only the first step in the formal rulemaking process. Thus, the actual relief requested in plaintiff's citizen petition—that menthol be added to the flavor ban—remains, at best, years away.

Defendants have now filed a second motion to dismiss, claiming that since they intend to ban menthol some of plaintiffs' claims are moot and others fail to state a claim. Defendants' arguments mostly repackage the same core concept that the Court already rejected in ruling on their last motion to dismiss—defendants' view that they can satisfy their Tobacco Control Act obligation with an endless series of "tentative determinations" and continuous "evaluations," none of which are judicially reviewable.

This is not the law, and the court should deny defendants' latest motion. Plaintiffs' claims are not moot because there remain several forms of effective relief that the Court can grant. First and foremost, the Court can order defendants to issue a NPRM by a date certain. It can also order defendants to complete the rulemaking process by a reasonable date. Even if no further relief were available, jurisdiction remains under the "voluntary cessation" exemption to the mootness doctrine. Defendants have never conceded their conduct was wrongful, and have made no permanent changes designed to address their ongoing unlawful delay. Instead, they insist that "[t]here is no required deadline or timeline for FDA to make a determination about what regulatory action, if any, is appropriate." FDA Response at 5 n.9. Finally, defendants own statements and authorities confirm that plaintiffs may assert claims under 5 U.S.C. § 706(1) for defendants' unlawful delay in acting on their citizen petition "approval" and "determination."

In sum, the supplemental complaint states a claim and has not been mooted by defendants' latest statement of intent to ban menthol. The Court should receive evidence concerning defendants' unlawful delay and then award plaintiffs their requested relief.

BACKGROUND

I. The Tobacco Control Act

In 2009, Congress passed the Tobacco Control Act, which among other things, empowered FDA to regulate cigarettes and tobacco products by establishing "tobacco product standards." *See* 2d Am. Compl. (1st Suppl.) ¶¶ 2, 53. Relevant here, the Act created a "flavor ban"—i.e., a product standard banning all flavors in cigarettes other than menthol and tobacco. *Id.* ¶¶ 2, 53 (citing 21 U.S.C. § 387g(a)(1)). The Act also required FDA to "provide for periodic evaluation of tobacco product standards established under this section [including the flavor ban] to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." 21 U.S.C. § 387g(a)(5).

Although the flavor ban initially omitted menthol, Congress mandated that FDA create a scientific advisory committee to immediately begin gathering information on menthol and to evaluate whether the flavor ban should be changed to reflect that new information. "Congress observed that menthol cigarettes 'may pose unique health risks to those who smoke them,' and that it was "especially concerned about proportionately higher rates of menthol cigarette use among African American smokers." MTD Order (citing FAC ¶ 3; H.R. Rep. No. 111-58, pt. 1, at 38 (2009).) As a result, the Act "specifically directed the FDA to create a Tobacco Products Scientific Advisory Committee ('Committee'), and to immediately refer to the Committee for a report and recommendation on 'the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.'" MTD Order at 2 (citing FAC ¶ 4; 21 U.S.C. § 387g(3)(1).)[1]

In 2011, the Committee released its report, concluding: "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." MTD Order at 2 (citing

[1] The Act's legislative history confirms that Congress considered menthol to be an urgent public health concern and intended the FDA to take specific steps to address it. *See* 2d Am. Compl. (1st Suppl.) ¶ 63. Indeed, the bill's accompanying Committee Report emphasized the Committee's "belie[f] that it is critical for the Secretary to move quickly to address the unique public health issues posed by menthol cigarettes. *Id.* ¶ 64 (emphasis added).

FAC ¶ 6.) In 2013, the FDA conducted a peer-reviewed investigation, which concluded that the use of menthol cigarettes was associated with increased smoking initiation, and likely posed "a public health risk above that seen with nonmenthol cigarettes." *Id.* In July 2013, FDA also issued an advance notice of proposed rulemaking to solicit information and public comment on the "potential regulation of menthol in cigarettes." 2d Am. Compl. (1st Suppl.) ¶ 99.

Despite these pronouncements, for the next several years, the FDA took minimal, if any, action on menthol. *See id.* ¶ 147. Finally, five years later (in 2018), then-FDA Commissioner Scott Gottlieb conceded that "[i]t was a mistake for the agency to back away" on menthol, and announced that the FDA would advance a "Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars." *Id.* ¶¶ 122, 125. But FDA took no action.

II. Procedural History

A. Plaintiffs File Suit to Compel Agency Action.

As a result of defendants' inaction, plaintiffs African American Tobacco Control Leadership Council and Action on Smoking and Health filed their complaint on June 17, 2020, alleging violations of the Tobacco Control Act and Administrative Procedure Act ("APA"). *See* Compl. (ECF No. 1).[2] Specifically, plaintiffs alleged that defendants had (a) unduly delayed and unlawfully withheld agency action—including failing to periodically evaluate the flavor ban "to determine whether such standard[] should be changed to reflect new medical, scientific, or other technological data," as required by 21 U.S.C. § 387g(a)(5) (Count I); (b) unduly delayed and unlawfully withheld a substantive response to plaintiff African American Tobacco Control's 2013 Citizen Petition, which sought a tobacco product standard banning menthol in cigarettes (Count II); and (c) in the alternative, made a determination not to ban menthol, and that this decision was arbitrary and capricious (Count III). *See id.*

[2] Plaintiffs' complaint was later amended to add the American Medical Association and National Medical Association as co-plaintiffs. *See* 1st Am. Compl. (ECF No. 19); 2d Am. Compl. (ECF No. 41).

B. The Court Denies Defendants' First Motion to Dismiss.

Defendants filed their first motion to dismiss on September 18, 2020, arguing that Counts I and III should be dismissed for lack of subject matter jurisdiction. *See* Defs.' Br. and Proposed Order (ECF Nos. 26, 26-1). Defendants claimed that their intended response to the Citizen Petition would render Count II moot, and as a result, did not move to dismiss Count II.

This Court rejected defendants' motion as to Count I. Defendants "argued that this section imposes no duty to revise existing tobacco product standards or adopt new ones, but only requires 'periodic evaluations,' a requirement that the FDA has satisfied by undertaking evaluations of menthol cigarettes." MTD Order at 4. The Court rejected this view, holding that the Tobacco Control Act required FDA to "not only make periodic evaluations, but to make a determination of whether to *modify* the standard, which may include adding menthol cigarettes to the flavor ban." MTD Order at 4 (emphasis in original); *see also id.* at 8. An "evaluation" was insufficient, as were "tentative decisions" by the agency. *Id.* at 8. Moreover, to the extent defendants were suggesting "that they are permitted to not make a final decision indefinitely, this could constitute a failure to act in a reasonable amount of time." *Id.*[3]

C. Defendants' April 29, 2021 "Final Response" and "Determination."

Following this Court's Order, defendants agreed "to issue a final response to plaintiffs' Citizen Petition by January 29, 2021." *See* Stipulation, 2 (ECF No. 39). This deadline was later extended to April 29, 2021, to account for plaintiffs' supplementation of their Citizen Petition and defendants' change in leadership. *See* ECF Nos. 39–40, 43–44.

Finally, on April 29, 2021—after roughly eight years—the FDA provided a substantive response to the plaintiffs' 2013 Citizen Petition. *See* 2d Am. Compl. (1st Suppl.) ¶ 140.[4] The

[3] As to Count III, the Court granted the defendants' motion without prejudice, based on defendants' representation that they had not affirmatively decided to allow menthol to remain unregulated. *See id.* at 9. In the event the FDA later made "a final decision not to regulate menthol cigarettes," plaintiffs could bring their claim at such time. *Id.*

[4] A copy of FDA's April 29, 2021 Response to plaintiffs' Citizen Petition ("FDA Response") was previously filed with this Court, in conjunction with the parties' May 2021 Joint Case Management Statement, *see* ECF No. 50-1.

response stated: "Your petition requests that the Food and Drug Administration (FDA) prohibit menthol as a characterizing flavor in cigarettes. Specifically, your petition requests that FDA: (1) add menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarette and cigarette smoke directed by section 907(a)(1)(A)" of the Tobacco Control Act. *Id.* (citing FDA Response at 1). FDA "interpret[ed 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," and stated that "FDA intends to take such action. … FDA therefore grants [the petition] in accordance with 21 C.F.R. § 10.30(e)(3)." *See* 2d Am. Compl. (1st Suppl.) ¶ 140 (citing FDA Response at 2). FDA explained that its decision was based on "existing scientific evidence in the record," which demonstrated that "eliminating menthol as a characterizing flavor in cigarettes would benefit public health." *Id.* ¶ 140 (citing FDA Response at 10).

FDA "note[d] that the petition did not provide the exact wording of the proposed regulation, as required by 21 C.F.R. § 10.30(b)(3)." FDA Response at 8 n.26. However, "add[ing] menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarettes and cigarette smoke directed by section 907(a)(1)(A) of the Tobacco Control Act," as the petition requested, *see* Petition at 4–5, can be easily accomplished through a few minor changes to the Act's existing language:

> [A] cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco ~~or menthol~~) or an herb or spice, including menthol (whether synthetic or natural), strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

See 21 U.S.C. § 387g(a)(1)(A) (noting proposed changes in red underline and strikeout).

Unfortunately, however, FDA's Response reflected that it had not taken any of the formal steps required to initiate rulemaking or set a deadline to do so. Instead, it emphasized that the

Tobacco Control Act "[did] not require or compel FDA to adopt any particular tobacco product standard within any specific time frame." *See* 2d Am. Compl. (1st Suppl.) ¶ 140 (citing FDA Response at 3). FDA also noted that it possessed "broad discretion in deciding whether or not to issue, revise, amend, or revoke an existing product standard[.]" *Id.* And perhaps most tellingly, FDA's Response repeated an earlier statement by the agency that "[t]here is no required deadline or timeline for FDA to make a determination about what regulatory action, if any, is appropriate." *Id.* (citing FDA Response at 5, n. 9). In essence, FDA's Response suggested that the agency could drag out the rulemaking process—*i.e.*, FDA's ultimate determination of whether to ban menthol in cigarettes—indefinitely.

The Commissioner also published a one paragraph letter that stated, in its entirety:

> On April 29, 2021, the citizen petition filed April 12, 2013, from Tobacco Control Legal Consortium (now known as the Public Health Law Center), the African American Tobacco Control Leadership Council, and others regarding banning menthol as a characterizing flavor in cigarettes was granted. In accordance with 21 CFR 10.30(e)(2)(i), I am directing the Center for Tobacco Products to engage in the rulemaking process by promptly beginning to draft the proposed rule.

2d Am. Compl. (1st Suppl.) ¶ 144. The letter contained no further details concerning the timing or substance of any proposed rule, or any other specific action to be taken by FDA or the Center for Tobacco Products.

On the same day, FDA announced the agency's intention "toward[s] issuing proposed product standards within the next year to ban menthol as a characterizing flavor in cigarettes[.]" FDA Apr. 29, 2021 News Release: FDA commits to Evid.-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers (Apr. 29, 2021)[5]; *see also* 2d Am. Compl. (1st Suppl.) ¶ 141. The news release noted that the agency's decision was based on "clear science and evidence," FDA Apr. 29, 2021 News Release, and that banning menthol "will help save lives, particularly among those disproportionately affected by these deadly products, … significantly

[5] *Available at* https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.

reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products." *Id.* ¶ 141.

D. Plaintiffs' Second Amended (First Supplemental) Complaint

Defendants' response to the Citizen Petition was a step in the right direction, but fell short of what the law requires. Plaintiffs accordingly supplemented their complaint to include these post-filing factual developments (described above), and defendants' related legal obligations.

First, 21 C.F.R. § 10.30(e) governs FDA's response to a citizen petition. It provides that "[t]he Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition," *id.* § 10.30(e)(1). If the petition is approved, then "the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval." *Id.* § 10.30(e)(2)(i) (emphasis added). The supplemental complaint alleges that defendants have not taken "appropriate action" to "implement[] the approval," and asks this Court to order them to do so. 2d Am. Compl. (1st Suppl.) ¶¶ 143–46.

Second, in response to defendants' characterization of "their recent statements of intent to ban menthol as a 'determination,' for purposes of 21 U.S.C. § 387g(a)(5)," the supplemental complaint alleges that the law requires such a determination to be in a more actionable form. 2d Am. Compl. (1st Suppl.) ¶ 155 (referencing 21 U.S.C. § 387g(a)(3)(b)(ii), which states that: "In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, …") (emphasis added).

Third, the supplemental complaint contends that defendants continue to unlawfully delay acting on menthol. FDA has been collecting and evaluating evidence on menthol since 2010, and this evidence has consistently shown that banning menthol from cigarettes would advance the public health. *See* 2d Am. Compl. (1st Suppl.) ¶ 142. Despite FDA's repeated acknowledgement

of the urgent public health issues at stake, it still has taken no action to formally commence the rulemaking process. *Id.* Indeed, FDA has suggested that it cannot commit to any firm deadline, but expects to take a year or more to publish such a notice. *See id.*

Given the history and the interests at stake, this timing is unreasonable. FDA does not write on a blank slate. The Tobacco Control Act already includes a flavor ban, which FDA can easily modify to include menthol. If anything, FDA should have been working on a notice of proposed rulemaking long before now, including following former-FDA Commissioner Gottlieb's statements in 2018. But to date, the agency has made no discernable progress and set no meaningful deadlines. *See id.* On this record, defendants' unexplained failure to proceed expeditiously with its own proposed rulemaking violates the Tobacco Control Act and APA.

Finally, the supplemental complaint emphasized that defendants' 2021 citizen petition response and purported determination *mirrored almost exactly* the statements made by former-FDA Commissioner Gottlieb nearly three years before in 2018. *See* 2d Am. Compl. (1st Suppl.) ¶ 145 (noting Dr. Gottlieb's statements in 2018 that FDA "armed with additional years of data" would advance a "Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars."). These statements were made well before plaintiffs commenced this action. There is no logic to defendants' position that by repeating these same statements post-filing, they have somehow mooted plaintiffs' claims. Plaintiffs therefore reiterate their request that defendants be directed to issue a Notice of Proposed Rulemaking.

LEGAL STANDARDS

"The party asserting mootness bears the burden of establishing that there is no effective relief that the court can provide. That burden is 'heavy'; a case is not moot where any effective relief may be granted." *Forest Guardians v. Johanns*, 450 F.3d 455, 461 (9th Cir. 2006). This may include relief not specifically requested in the complaint. "The question is not whether the precise relief sought at the time [the case] was filed is still available. The question is whether there can be any effective relief." *McCormack v. Herzog*, 788 F.3d 1017, 1024 (9th Cir. 2015).

Further, a defendant's voluntary cessation of allegedly unlawful conduct does not render the underlying controversy moot unless there is "no reasonable possibility that the challenged conduct will resume." 15 Moore's Fed. Practice – Civil § 101.99 (2021) (citing cases). In these circumstances, the party asserting mootness bears the "heavy burden" of showing that the challenged conduct is unlikely to recur. *See, e.g., Logan v. U.S. Bank N.A.*, 722 F.3d 1163, 1166 (9th Cir. 2013) (noting that the defendant failed to meet "formidable burden" of showing that it was "absolutely clear" the allegedly wrongful behavior could not reasonably be expected to recur).

Finally, as defendants concede, in evaluating whether defendants have met their "heavy burden" to show mootness, as well as whether plaintiffs' complaint states a claim for purposes of Rule 12(b)(6), "the court assumes that [plaintiff's] factual allegations are true," 2d MTD at 10, and "construe[s] them in the light most favorable to the plaintiff." *Irving Firemen's Relief & Ret. Fund v. Uber Techs., Inc.*, 998 F.3d 397, 403 (9th Cir. 2021).

ARGUMENT

Plaintiffs' claims are not moot because the Court can grant effective relief, and also because defendants have not shown that their voluntary cessation of unlawful conduct is permanent. In addition, drawing all inferences in plaintiffs' favor, the complaint states a claim under 5 U.S.C. § 706(1)—despite now conceding that the evidence supports a ban on menthol in tobacco products, defendants are still unlawfully withholding and unreasonably delaying action implementing a menthol ban, including the issuance of a NPRM.

I. Defendants improperly dispute Plaintiffs' allegations, and no evidence supports their assertions.

As a threshold matter, defendants' motion should be denied because—despite conceding that the Court must accept plaintiffs' allegations as true for purposes of this motion, 2d MTD at 10—defendants' motion relies heavily on (1) assertions that "Plaintiffs' submissions mistakenly assume," facts that defendants dispute, 2d MTD at 6; and (2) "facts" outside the Complaint asserted by defendants' in their motion papers. For example, defendants argue that plaintiffs' allegations that FDA has not commenced the rulemaking process are wrong, *id.*, and assert that

"FDA has entered the second phase of the rulemaking process … and is now drafting the NPRM," *id.* at 7; *see also id.* at 8 (asserting that "FDA is working expeditiously to complete the second phase of the rulemaking process").

There is no evidence that FDA is now drafting the NPRM, and these "bare assertions" cannot demonstrate mootness.[6] If defendants wished to argue that they have—contrary to plaintiffs' allegations—begun the rulemaking process, they should have, at a minimum, submitted evidence of what actions they are allegedly taking. Instead, defendants rely on a generic description of how the rulemaking process was being conducted before 2009 (*see* 2d MTD at 6–7).[7] This failure alone is sufficient grounds for denying defendants' motion.

II. The Court can grant plaintiffs several forms of effective relief.

Defendants have not carried their heavy burden to show that no effective relief can be granted. In fact, although defendants style their brief as a motion to dismiss the complaint as moot, the motion papers concede that only a small portion of the relief sought in the complaint has already been provided. 2d MTD at 14 (arguing, incorrectly, that plaintiffs' "additional demands do not raise any plausible relief that the Court could legally grant under the APA").

Defendants' arguments are based on the incorrect premise that "[d]espite the changed factual circumstances since the commencement of this lawsuit, Plaintiffs' have not altered their

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[6] *See Armster v. U.S. Dist. Ct. for Cent. Dist. of California*, 806 F.2d 1347, 1359 (9th Cir. 1986) ("The bare assertion by the Justice Department in its mootness motion that this situation will not recur is far from credible. Nor would it in any event be sufficient to deprive this Court of its constitutional power to adjudicate this case.") (quoting *United States v. Concentrated Phosphate Export Association*, 393 U.S. 199, 203 (1968) ("[H]ere we have only appellees' own statement that [the challenged actions would not recur]. Such a statement, standing alone, cannot suffice to satisfy the heavy burden of persuasion which we have held rests upon those in appellees' shoes.").

[7] Defendants also take significant liberties in their citations. For example, defendants cite Government Accountability Office, GAO-09-205, Federal Rulemaking 11-12 (2009) (available at https://www.gao.gov/products/gao-09-205) for the following propositions: "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.*" The Court will be hard-pressed to find these statements at the cited source.

requests for relief." *Id.* at 11. But as explained above, plaintiffs' amended complaint does seek additional relief, including:

- An order directing defendants to take "appropriate action" to implement the approval of the citizen petition's request for a menthol ban, as 21 C.F.R. § 10.30(e)(2)(i) requires;
- An order that defendants' purported "determination" that the flavor ban should be updated to include menthol be made in the statutorily required form, *i.e.* a tangible action to implement the determination, and not a mere statement of intent to act on an uncertain timeline (which amounts to precisely the same "tentative determination" concept that the Court has already rejected); and
- An order directing defendants to implement the menthol ban within a reasonable timeframe, beginning with prompt publication of a NPRM.

2d Am. Compl. (1st Suppl.) ¶¶ 160–62, 168, Relief Requested. Further, the question is whether there is any effective relief the Court can grant, not whether that exact form of relief is requested in the complaint. *McCormack*, 788 F.3d at 1024 ("The question is not whether the precise relief sought at the time [the case] was filed is still available."); *see also Bayer v. Neiman Marcus Grp., Inc.*, 861 F.3d 853, 869 (9th Cir. 2017) (holding that claim for nominal damages was not mooted, "[t]hough Bayer did not state a separate claim for nominal damages in his complaint").

Courts regularly reject mootness claims where, as here, there remains additional relief that can be granted. For example, in *Leigh v. Salazar*, 677 F.3d 892, 897 (9th Cir. 2012) the court held that an injunction request was not moot even though one action covered by the injunction had already occurred (and thus could not be enjoined). The injunction "could apply to future" activities, and plaintiff had other outstanding requests. *Id.* The case *Haynes v. Hooters of Am., LLC*, 893 F.3d 781, 784–85 (11th Cir. 2018) is also instructive. There, the court held that while the defendant "may be in the process of updating the accessibility of its website, there is nothing in the record demonstrating that [it] has successfully done so. Accordingly, it cannot be said that the issues are no longer 'live' or that the parties lack a legally cognizable interest in the outcome." The same is true here. While FDA claims to be in the process of drafting a notice of proposed

rulemaking, there is nothing in the record demonstrating that it has successfully done so. Thus, plaintiffs' claims remain live.

The cases cited by defendants do not support their arguments. They generally stand for the uncontroversial proposition that when a party brings claims seeking to compel a decision those claims are moot when a decision is made—regardless of whether the plaintiff wished a different result. And none involve a defendant who makes a decision plaintiffs agree with, but refuses to implement it within a reasonable timeframe. For example, in *Kuzova v. U.S. Dept. of Homeland Sec.*, 686 Fed. App'x 506, 508 (9th Cir. 2017), the Court concluded that since the plaintiff had been granted citizenship under one statutory provision, his claim for citizenship under another provision was moot: "Although Kuzov argues that citizenship granted under § 1440 is somehow less desirable than citizenship granted under 8 U.S.C. § 1427, we know of no differences in a person's rights based upon which route was used to obtain citizenship." *Id.* at 508. Similarly, in *W. Radio Servs. Co. v. U.S. Forest Serv.*, No. CIV. 04-1346-AA, 2008 WL 427787, at *5 (D. Or. Feb. 12, 2008), the complaint sought a decision on four antennae construction permits. Two were granted and two were denied, and the court concluded that: "[a]lthough the Forest Service's Decision Notice was not completely favorable to Western Radio, no action remains to be taken with respect to the sidehill antenna application." *Id.* (emphasis added).

In *Schirripa v. Gottlieb*, No. 17-CV-1060 (CRC), 2018 WL 4567163, at *1 (D.D.C. Sept. 24, 2018), *aff'd sub nom. Schirripa v. Sharpless*, No. 18-5329, 2019 WL 3229439 (D.C. Cir. June 25, 2019), the Court ruled that FDA had mooted an undue delay claim by (belatedly) responding to the plaintiff's citizen petition. However, the response there was that FDA "lacked authority to undertake the actions" sought and thus FDA "declined" his proposal. Likewise, in *Friends of Animals v. Pruitt*, 258 F. Supp. 3d 91, 93 (D.D.C. 2017) and *Burk v. Food & Drug Admin.*, No. CV RDB-19-73, 2019 WL 2010195, at *1 (D. Md. May 6, 2019) (emphasis added), the citizen petitions were denied; thus, no further action was required and there was no relief the Court could grant. In addition, in *W. Radio Servs. Schirripa*, and *Pruitt*, the plaintiffs conceded the claims were moot; and *Burk* failed to oppose the motion to dismiss.

Importantly, all of these cases involve circumstances where there was no further action that could be taken by the government. The situation here is far different. Plaintiffs' core complaint is that defendants have failed to take appropriate and timely action concerning menthol—action that defendants now agree they should be taking. Thus, plaintiffs are not seeking to overturn defendants' denial of a citizen petition. They simply ask the Court to compel defendants to act on *FDA's own conclusion* that a menthol ban is necessary and appropriate.

Finally, defendants contend that *Ctr. for Biological Diversity v. Kempthorne*, 498 F. Supp. 2d 293, 297 (D.D.C. 2007) is particularly instructive. Plaintiffs agree—to a point.[8] There, the court concluded that plaintiff's claim for a decision on its citizen petition was mooted by a response granting the petition. Although plaintiff argued that its claim was not moot "because defendants have not instituted or proposed the modifications it requested in its petition," the court found this argument was "beyond the scope of plaintiff's complaint," which sought only "a decision regarding plaintiff's petition." *Id.* at 297. The court dismissed the claim as moot, but specifically noted that its holding did not prevent plaintiff from pursuing alternate claims "if defendants do not complete the rule-making process … within a reasonable period of time." *Id.*

Again, the situation is far different here. Plaintiffs have always sought broader relief than a decision on their citizen petition, up to and including a menthol ban. And plaintiff's supplemental complaint makes clear that they take specific issue with the "defendants' unexplained and unjustifiable failure to proceed expeditiously with its own proposed rulemaking to ban menthol in combustible tobacco products." 2d Am. Compl. (1st Suppl.) ¶ 146; *see also id.* ¶ 168 ("On April 29, 2021, FDA responded to the Citizen Petition stating that it was granting the petition and intended to ban menthol-flavored cigarettes and cigars. However, defendants did not "concurrently take appropriate action … implementing the approval," as 21 C.F.R. §

[8] Defendants' description of this case as holding that the plaintiff "could not overcome mootness of its unreasonable delay claim by anticipating future delays in the regulatory process" is wrong. This concept appears nowhere in the opinion.

10.30(e)(2)(i) requires.").[9] Thus, following the logic of *Ctr. for Biological Diversity*, plaintiffs' claims here are not moot. Instead, that case confirms that plaintiffs may pursue their claims based on the agency's failure to publish a notice of proposed rulemaking.

In any event, *Ctr. for Biological Diversity* is distinguishable. The Ninth Circuit does not limit the mootness analysis to the exact relief sought in plaintiff's complaint. *McCormack*, 788 F.3d at 1024; *Bayer*, 861 F.3d at 869; *Fikre v. Fed. Bureau of Investigation*, 904 F.3d 1033, 1040–41 (9th Cir. 2018) (finding that claim was not moot, including because a "declaration" that certain safeguards would be implemented could "constitute additional relief that may be afforded to Fikre," noting that "[w]hen examining whether a claim has become moot, "[t]he question is not whether the precise relief sought at the time [the case] was filed is still available.") (quoting *McCormack*, 788 F.3d at 1024).

In sum, there are numerous forms of effective relief the court could provide here; they are alleged in the complaint, which the court should construe in the light most favorable to plaintiffs; and even if they were not, the Court could still consider them in determining whether the plaintiffs' claims are moot. Defendants have failed to meet their heavy burden of showing that the court cannot grant any effective relief. *See Chafin v. Chafin*, 568 U.S. 165, 177 (2013) (rejecting mootness claims because "Mr. Chafin's requested relief is not so implausible that it may be disregarded on the question of jurisdiction; … even the availability of a partial remedy is sufficient to prevent a case from being moot.") (citation and internal quotations omitted).

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[9] *Also compare Ctr. for Biological Diversity*, 498 F. Supp. at 297 n.7 ("the fact that defendants have not published any rule changes in the Federal Register does not prohibit plaintiff's claim from being moot because the issue of publishing a proposed rule change in the Federal Register is not in the complaint") *with* 2d Am. Compl. (1st Suppl.) ¶ 144 ("Here, instead of concurrently taking appropriate action to implement the approval—i.e., by "engag[ing] in the rulemaking process by proposing a rule [in the Federal Register] to prohibit menthol as a characterizing flavor in cigarettes," …—the Commissioner published a one paragraph letter "directing the Center for Tobacco Products to engage in the rulemaking process by promptly beginning to draft the proposed rule.") (emphasis added).

III. Defendants' voluntary cessation of their unlawful conduct does not moot Plaintiffs' claims.

Defendants' motion also fails because defendants have not demonstrated that it is absolutely clear their unlawful conduct will not reoccur. As noted above, the voluntary cessation of challenged conduct by a defendant does not render the underlying controversy moot unless there is "no reasonable possibility that the challenged conduct will resume." 15 Moore's Fed. Practice – Civil § 101.99 (2021). Thus, the party asserting mootness bears the "formidable burden" of showing that it is "absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Logan*, 722 F.3d at 1166.

This "heavy burden" applies to a government entity "that voluntarily ceases allegedly illegal conduct." *Bell v. City of Boise*, 709 F.3d 890, 898–99 (9th Cir. 2013) (citations and internal quotations omitted). To carry its burden, the government must demonstrate "that the change in its behavior is 'entrenched' or 'permanent.'" *Fikre*, 904 F.3d at 1037 (citation omitted).

When the government continues to assert, however, a right to engage in the allegedly wrongful conduct, despite having ceased the conduct at issue, this will generally preclude a finding of mootness. *See e.g. McCormack*, 788 F.3d at1025. Further, a federal agency's stated efforts at reform "would not automatically moot the case, because 'announcement of an intention to change or adoption of a plan to work toward lawful behavior' is generally insufficient to defeat an exception to mootness." *Rosemere Neighborhood Ass'n v. U.S. Environmental Protection Agency*, 581 F.3d 1169, 1173 n.3 (9th Cir. 2009) (reversing district court and holding that plaintiff's complaint was not moot). Likewise, "'when the relief sought is an order to the delaying agency to hurry up, but the agency acts 'to moot [the] case by acting before [the] claim for relief can be decided,' such a sequence 'begs for an exception to the ordinary rules of mootness.'" *Id.* at 1175 (quoting *Lucien v. Johnson*, 61 F.3d 573, 574–75 (7th Cir. 1995)). Finally, a pattern of delay by an agency "can be relevant to the mootness analysis," and may help convince a court that an action should go forward. *Id.* at 1173 n.3 (citing cases).

Here, plaintiffs' complaint alleges a long pattern of unlawful delay by defendants. In 2009, Congress directed defendants to address the "critical" public health issue of menthol in cigarettes, and to move "as quickly as practicable." But for nearly a decade, defendants did nothing with respect to their obligations under the Tobacco Control Act, and to plaintiffs' citizen petition. One of plaintiffs' primary complaints in this lawsuit has always been that defendants have unduly delayed and/or unlawfully withheld action on removing menthol from cigarettes, despite a growing body of evidence demonstrating the harms caused by menthol, and FDA's own conclusions that a ban would benefit public health. *See, e.g.*, 2d Am. Compl. (1st Suppl.) ¶¶ 18–19.

Defendants have made no showing that this pattern of delay and inaction has been corrected, much less permanently corrected. On the contrary, everything about defendants' citizen petition response reflects an effort to stall and avoid fulfilling their obligations. Thus, the unlawful conduct continues. "The steps taken by the" FDA toward "compliance, while commendable, have not addressed this problem. Therefore, this [matter] clearly cannot be considered moot." *Layton v. Elder*, 143 F.3d 469, 471–72 (8th Cir. 1998); *see also McCormack*, 788 F.3d at 1024 (claims were not mooted when defendant had "never repudiated the statute as unconstitutional, and he did not cease McCormack's prosecution because he believed the prosecution was unlawful.").[10]

What defendants have shown is a clear desire to avoid any judicial oversight. Defendants have made clear that their actions were designed not to ensure full compliance with their legal obligations, but primarily to put an end to this litigation. Well before they had taken any action, it was "[d[efendants' position that their anticipated response will provide all the relief available

[10] *See also Demery v. Arpaio*, 378 F.3d 1020, 1026 (9th Cir. 2004) (holding that a "temporary cessation" did not render the case moot because "the defendant intends to resume his behavior if he can and there has been no showing that recurrence is not technologically and otherwise feasible, [thus] it is reasonably likely that he will resume the contested [activity]"); *Rosemere Neighborhood Ass'n v. U.S. Environmental Protection Agency*, 581 F.3d 1169, 1175 (9th Cir. 2009) ("Our conclusion that this case is not moot is also supported by an additional fact: What the district court initially classified as an 'isolated instance of untimeliness' has since bloomed into a consistent pattern of delay by the EPA.").

under Plaintiffs' remaining claims: a final response to the citizen petition (the relief sought in Count II) containing a determination of whether to add menthol to the flavor ban (the relief sought in Count I)." Dkt No. 39.

The response itself claims to grant plaintiff's request for a tobacco product standard banning menthol, conceding that the relevant evidence unambiguously supports plaintiffs' request. But it contains no firm commitment to take any action implementing this supposed approval. Instead, it denies that the Tobacco Control Act "require[d] or compel[ed] FDA to adopt any particular tobacco product standard within any specific time frame," FDA Response at 8–14, asserts that FDA possesses "broad discretion in deciding whether or not to issue, revise, amend, or revoke an existing product standard," *id.*, and reiterates the agency's incorrect assertion that "[t]here is no required deadline or timeline for FDA to make a determination about what regulatory action, if any, is appropriate." *Id.* at 5, n. 9. This last assertion is particularly noteworthy, given the Court's ruling on defendants' last motion to dismiss already rejected the same argument: "Defendants also argue that the Tobacco Control Act imposes no statutory deadline, and therefore the FDA 'cannot be compelled to take such action now.' … As Plaintiffs point out, however, the Ninth Circuit has found that 'even though agency action may be subject to no explicit time limit, a court may compel an agency to act within a reasonable time' under the APA." MTD Order at 8.[11]

In other words, FDA's Response asserts that the agency can drag out the rulemaking process—i.e., FDA's ultimate determination of whether to ban menthol in cigarettes, and the action actually requested by plaintiff's citizen petition—indefinitely. It also refuses to acknowledge that based on the currently available evidence it would be arbitrary and capricious for the FDA to take no action on menthol. Nothing about this response reflects that any change in FDA's behavior is "entrenched" or "permanent." Indeed, it is unclear from this response

[11] *See Public Citizen Health Research Group v. Commissioner, Food & Drug Admin.*, 724 F. Supp. 1013, 1020 (D.D.C. 1989) (noting that "once the FDA [has] elected to respond to its legislative directive … the APA impose[s] an obligation to proceed with *reasonable* dispatch.").

whether FDA has in fact taken any new action on menthol—it merely repeats statements already made by Dr. Gottlieb in 2018, and does not reflect any rulemaking actions. Further, it disclaims any obligation or deadline to act on menthol. Such conduct is insufficient to moot claims.[12]

Although it is defendants' burden to show that it has permanently ceased its unlawful conduct (and not plaintiffs' burden to show that the conduct will recur), it is worth noting that defendant FDA has a long history of failing to act on its obligations. For example, in *Public Citizen Health Research Group v. Comm'r, Food & Drug Admin.*, 724 F. Supp. 1013, 1020 (D.D.C. 1989), the court held that FDA's issuance of a regulation "in the midst of litigation" did not moot the plaintiffs' complaint, given agency's "history of delays and missed deadlines [and] necessitat[ing] a court imposed schedule." *Id.* In addition, FDA's justification for its continued delay in promulgating a regulation was "lame at best and wholly irresponsible at worst." *Id.* at 1019–20. Here, defendants have offered no justification whatsoever for their continued delay.

This pattern of delay by FDA—not only with respect to the issue of menthol in cigarettes—is apparent in other public health matters overseen by the agency. *See, e.g., NRDC v. United States FDA*, 884 F. Supp. 2d 108, 119 (S.D.N.Y. 2012) (holding that FDA's 30+ years of inaction resulted in the agency's failure to perform its statutorily-prescribed duty to initiate and complete withdrawal of the FDA's approval of the use of certain antibiotics in livestock for non-therapeutic purposes, to be an unreasonable delay of agency action); *Tummino v. Torti*, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009) (holding that FDA's repeated delay in issuing a decision concerning Plan B was suspect, and the likely result of political considerations); *Cutler v. Hayes*, 818 F.2d 879, 900 (D.C. Cir. 1987) (noting that FDA's limited progress in completing its over-the-counter drug review, since its inception in 1972, had frustrated the achievement of the safety

[12] *See, e.g., Demery v. Arpaio*, 378 F.3d 1020, 1026 (9th Cir. 2004) (holding that a "temporary cessation" did not render the case moot because "the defendant intends to resume his behavior if he can and there has been no showing that recurrence is not technologically and otherwise feasible, [thus] it is reasonably likely that he will resume the contested [activity]"); *Rosemere*, 581 F.3d at 1175 ("Our conclusion that this case is not moot is also supported by an additional fact: What the district court initially classified as an 'isolated instance of untimeliness' has since bloomed into a consistent pattern of delay by the EPA.").

and efficacy goals of the 1963 Amendments, and therefore constituted an unreasonable agency delay); *Public Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 34 (D.C. Cir. 1984) (observing that the "current record strongly suggests that the pace of [FDA] agency decision making is unreasonably dilatory" and was "particularly troubling" given that FDA's slow agency decision making "may jeopardize the lives of children").

Defendants have not established mootness because they have not demonstrated that their claimed voluntary cessation of unlawful conduct is permanent. It is far from clear that defendants have even ceased their unlawful delay and inaction on menthol. Their own submissions confirm they do not admit their conduct was unlawful. Instead, they insist that they have unfettered discretion to take any action or no action on menthol. In short, plaintiffs' claims are not moot.

IV. Plaintiffs' Demands for Rulemaking State a Claim

The Court can furthermore enter an order directing defendants to publish a NPRM banning menthol on a date certain, and impose a schedule for completion of the rulemaking process. This relief is available under 5 U.S.C. § 706(1), which authorizes courts to "compel agency action unlawfully withheld or unreasonably delayed."[13]

1. The Tobacco Control Act Requires that Defendants' "Determination" to Ban Menthol Be Embodied in a NPRM

Plaintiffs do not, as defendants would have it, "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 MTD at 14 (emphasis added). What plaintiffs allege is that when, as here, defendants claim to have made a determination to implement a new

[13] *See, e.g., Public Citizen v. Comm'r, Food & Drug Admin.*, 724 F. Supp. at 1022 (finding "good cause" to "require the agency [FDA] to promulgate its final regulation on standardizing tampon absorbency labeling by October 30, 1989 [i.e., 60 days from the Court's Order] and [hold] that this rule will become effective … at the same time" where "FDA's response to its obligation to protect the public from the dangers associated with Toxic Shock Syndrome has been unreasonable" and "[i]ts delay in promulgating a final rule reflect[ed] an insensitivity to a long-existing and clearly identifiable problem"—a delay that was "particularly disturbing since the public health and human lives are at stake.").

or modified tobacco product standard (as opposed to a determination that no change is appropriate), *that determination* must be accompanied by implementing action, *i.e.* publication of a NPRM in the Federal Register.[14]

21 U.S.C § 387g(a)(3)(b)(iii) provides clear guidance on what it means to make a "determination" of this nature for purposes of 21 U.S.C § 387g(a)(5). That provision explains that when the Secretary "makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product," a party objecting to the proposal may provide scientific evidence for consideration. *Id.* (emphasis added.)

Defendants argue that this provision is irrelevant because it "only applies to *new* 'tobacco product standards' that are adopted '*in addition* to those in paragraph (1)'" while FDA intends "to amend the *existing* flavor ban established in 'paragraph (1).'" 2d MTD at 15. But this is incorrect. Defendants admit that the process for amending the existing flavor ban is the same that would be used for new product standards, and offer no explanation of why determination would mean something different in the context of an amendment rather than an initial rulemaking. 2d MTD at 6–7; *id.* at 16 ("21 U.S.C § 387g(a)(2) and (c) 'require FDA to use notice-and-comment rulemaking when revising an existing tobacco product standard.'"). Plaintiffs "attach special significance to publication of a 'notice' in the Federal Register," MTD at 14, because that is the mechanism by which defendants must formally commence the rulemaking process.

Defendants' argument that § 387g(a)(3)(b)(iii) "simply permits 'any party objecting' to a proposed new product standard to provide" evidence for consideration also misses the point. Plaintiffs do not argue that this provision mandates the form of determination, only that it provides clear evidence of what Congress intended that term to mean in other areas of the

[14] Counsel's comments at the hearing about the form of delivery are taken out of context, and did not suggest that FDA could make a "determination" to ban menthol without issuing a NPRM to that effect. Further, defendants are public officials and agencies. They cannot avoid their obligations under the Tobacco Control Act based on such statements.

statute, which should be read consistently with this one. *United States v. Cabaccang*, 332 F.3d 622, 627 (9th Cir. 2003) (en banc) ("[W]e must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous.") (citations omitted).

In addition, defendants' interpretation is illogical—what would be the point of a determination that is never implemented? That is why 21 U.S.C § 387g(a)(3)(b)(iii) discusses a "determination" to require elimination of additives in the context of a "proposed tobacco product standard in a proposed rule." Most importantly, defendants' position is inconsistent with this Court's rejection of the same "tentative determination" concept that defendants argued unsuccessfully in their last motion to dismiss. The court should reject defendants' transparent repackaging of this argument for the same reasons given in its prior decision.

2. 21 C.F.R. § 10.30(e)(2)(i) Requires that Approval of the Citizen Petition Be Implemented by a NPRM.

Similarly, while a response denying a Citizen Petition could take several forms, a response approving a Citizen Petition "shall" by accompanied by "appropriate action (e.g., publication of a Federal Register notice) implementing the approval." 21 C.F.R. § 10.30(e)(2)(i) (emphasis added). This regulation prevents agencies from following the course defendants attempt to chart here—stating that they are "approving" a petition, without taking any meaningful action to effectuate the alleged approval. Plaintiffs' interpretation is consistent with the statutory language, and agency practice in other matters. For instance, in *Conservation Force, Inc. v. Jewell*, 733 F.3d 1200, 1204 (D.C. Cir. 2013), the defendant issued a favorable ruling on the plaintiff's "petition for a rule to downlist" a particular species. The response to the petition "was favorable … [and], it was accompanied by a proposed rule to downlist the species."

Defendants' interpretation, on the other hand, is illogical and inconsistent with the plain language of the regulation. Defendants have had more than eight years to consider their citizen petition response, and have amassed a wealth of relevant data. The purpose of the petition was for defendants to actually do something with the information. FDA concedes that plaintiffs

requested the agency issue a rule banning menthol flavoring in cigarettes and they claim to have granted that request. 21 C.F.R. § 10.30(e)(2)(i) requires some action actually "implementing the approval," and that action must take place "concurrently" with the approval. Indeed, defendants note that a petition would typically include the text of a proposed rule that could be issued as a NPRM. Response at 8 n.26. Here, given that the statute already contains a flavor ban exempting menthol the petition was clear that a proposed rule could simply alter that provision so that menthol was no longer exempted. *See* Section II.C, *infra*.

Defendants cite no authority in support of their argument that they can "grant" plaintiff's citizen petition and make a "determination" to ban menthol by simply stating their intention to do so. Absent a final rule, such "action" is meaningless. That is doubly true here, given FDA's same statements in 2018 and resulting inaction. Accordingly, this Court should reject defendants' interpretation here and avoid statutory constructions that would render these provisions meaningless. *See Li v. Eddy*, 324 F.3d 1109, 1110 (9th Cir. 2003).

3. The Complaint states a claim under 5 U.S.C. § 706(1) based on defendants' failure to timely issue a NPRM.

Finally, defendants argue that plaintiffs' complaint should be dismissed because not enough time has passed since FDA has provided its April 29 response to plaintiffs' citizen petition. *See* MTD at 18–19. In other words, defendants argue that this Court should forgo the full "TRAC" factor analysis that normally applies to such undue delay claims, in favor of dismissal under Rule 12(b)(6). That suggestion should be rejected out of hand.

To begin, defendants do not seriously contend that they are not ultimately required to issue a NPRM to implement the menthol ban. Indeed, defendants implicitly concede that plaintiffs can assert claims for unreasonable delay in implementing the citizen petition response and the purported "determination." *See* 2d MTD at 19.

Second, as far as this counsel has been able to determine, cases in which courts dismiss undue delay claims under Rule 12(b)(6) are rare. Defendants rely on *Kripke v. U.S. Food & Drug Admin.*, 730 F. App'x 486, 487–88 (9th Cir. 2018), but that unpublished case has little in common

with this one. *Kripke* held that "FDA's failure to resolve Kripke's complex citizen petition within seven months of its filing was not unreasonable—Kripke's petition included over 100 references and eight requests concerning at least ten previously approved drugs." The court noted that under 21 C.F.R. § 10.30(e)(2) the agency "shall furnish a response to each petitioner within 180 days of receipt of the petition," and that "FDA provided Kripke with an interim response stating that it was unable to reach a decision" as "expressly permitted by 21 C.F.R. § 10.30(e)(2)(iv)." *Kripke*, 730 F. App'x at 487. In other words, FDA had complied with the regulation's timeline.[15]

Here, as detailed in the complaint, defendants have taken eight years to address plaintiffs' citizen petition. Analysis concerning the feasibility and drafting of a proposed rule must have formed part of the agency's decision to grant the petition. The question currently before the court is whether it is reasonable for the agency to now take another year or more to publish a NPRM implementing that decision, and who knows how long after that to complete the rulemaking process and actually ban menthol—the action requested by plaintiffs' citizen petition.

Finally, even if the Court accepts defendants' dubious argument that they have reset the clock by "approving" the petition without accompanying action, the Court may still determine that the TRAC factors support plaintiffs' undue delay claims here. The complaint alleges—and defendants do not dispute—that lives are at stake. It also alleges that Congress expected defendants to act swiftly to address menthol, but that defendants have instead engaged in years of delay and inaction. Whatever weight defendants' arguments might have if they were acting on a blank slate, given the extensive history of delay alleged in the complaint, the Court should not dismiss such claims without a full evidentiary analysis concerning the applicable "TRAC" factors.

CONCLUSION

For all of the above reasons, the Court should deny defendants' second motion to dismiss.

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[15] The decision *In re Cal Power Exch. Corp.*, 245 F.3d 1110, 1125 (9th Cir. 2001) that there was no undue delay in addressing "retroactive refund requests" on power sales after a "four-month delay" is equally inapposite. The case involved a mandamus petition, not a Rule 12(b)(6) motion. And there was no statutory indication of urgency, no history of prior delay by the agency, and the interests at stake were purely economic.

Date: July 7, 2021
New York, NY

Respectfully submitted,

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