No. _____

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

IN RE BREAST CANCER PREVENTION PARTNERS;
CENTER FOR ENVIRONMENTAL HEALTH; CENTER FOR FOOD SAFETY;
CENTER FOR SCIENCE IN THE PUBLIC INTEREST;
ENVIRONMENTAL DEFENSE FUND;
ENVIRONMENTAL WORKING GROUP;
NATURAL RESOURCES DEFENSE COUNCIL, INC.; and
WE ACT FOR ENVIRONMENTAL JUSTICE;

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and
SCOTT GOTTLIEB, Commissioner,

Respondents.

PETITION FOR WRIT OF MANDAMUS

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CORPORATE DISCLOSURE STATEMENT REQUIRED BY FRAP 26.1

Petitioners Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Defense Fund, Environmental Working Group, Natural Resources Defense Council, Inc., and WE ACT for Environmental Justice have no parents, subsidiaries, or affiliates that have issued shares or debt securities to the public.

Respectfully submitted this 2nd day of May, 2018.

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INTRODUCTION

Petitioners Breast Cancer Prevention Partners; Center for Environmental Health; Center for Food Safety; Center for Science in the Public Interest; Environmental Defense Fund; Environmental Working Group; Natural Resources Defense Council, Inc.; and WE ACT for Environmental Justice (collectively "Petitioners") respectfully request a writ of mandamus from this Court to compel the U.S. Food and Drug Administration ("FDA") to decide Petitioners' Food Additive Petition No. 5A4810 ("Petition" or "Food Additive Petition"), seeking rescission of FDA's approval of seven carcinogenic food additives ("carcinogenic flavors" or "flavors"). The Federal Food, Drug, and Cosmetic Act ("Food Act"), 21 U.S.C. §§ 301 *et seq.*, which aims to protect the public from unsafe food and other dangerous products, prohibits the use of any food additive found to induce cancer in humans or animals. After FDA approved the seven flavors at issue for use in food, credible scientific evidence from multiple sources—including the National Toxicology Program, FDA's sister agency at the U.S. Department of Health and Human Services—established that each of these flavors induces cancer in humans or animals. Accordingly, the flavors are *per se* unsafe and cannot lawfully be approved for use in food.

In light of this scientific evidence, Petitioners submitted the Petition urging FDA to revoke its regulation approving the flavors for use in food. After some

discussion and amendment, FDA set a final "filing date" of February 10, 2016 for the Petition.[1] Under the Food Act, FDA had a mandatory obligation either to amend the regulation establishing the conditions under which these flavors may be safely used or to deny the Petition within 180 days of that filing date—that is, by August 8, 2016. To date, FDA has failed to decide the Petition, unlawfully withholding action in violation of the Food Act. This failure to act undermines the central purpose of the Food Act and perpetuates an ongoing risk of harm to Petitioners' members. A writ of mandamus is both necessary and appropriate to compel FDA to comply with its statutory obligation and decide the Petition.

THE RELIEF SOUGHT

Petitioners respectfully request that this Court issue a writ of mandamus ordering FDA to issue a final decision, within 30 days, on Petitioners' Food

[1] As discussed in Section IV *infra*, Petitioners submitted the Petition on July 28, 2015, and FDA filed it on August 17, 2015. *See* Filing of Food Additive Petition, 81 Fed. Reg. 42 (Jan. 4, 2016). After filing the Petition, FDA requested that Petitioners amend the Petition to include "*all* recent publications . . . for each flavoring additive identified regarding their safety." Letter from Judith Rabaglia, FDA, to Tom Neltner, Envtl. Def. Fund 1 (Dec. 17, 2015), attached hereto as Exhibit 5. FDA implied that it would deny the Petition "on the basis that there is insufficient information" if Petitioners refused to provide the requested, exhaustive literature review. *Id.* at 2. Petitioners submitted the review to FDA on February 10, 2016. Letter from Tom Neltner, Envtl. Def. Fund, to Judy Kidwell, FDA (Feb. 10, 2016), attached hereto as Exhibit 6. FDA deemed this information to be a substantive amendment to the Petition and, therefore, set a new, final filing date of February 10, 2016. Letter from Judith Rabaglia, FDA, to Tom Neltner, Envtl. Def. Fund 1 (Feb. 12, 2016), attached hereto as Exhibit 7. Accordingly, February 10, 2016, is the relevant filing date for this Petition.

Additive Petition, which seeks the rescission of FDA's approval of seven carcinogenic food additives now that appropriate scientific testing shows that these flavors induce cancer in humans or animals such that FDA's continued approval of their use violates 21 U.S.C. § 348(c)(3)(A) (the "Delaney Clause").

STATEMENT OF JURISDICTION

This Court has jurisdiction to review Petitioners' request for a writ of mandamus. Under the Food Act, the U.S. Courts of Appeals have exclusive jurisdiction to review any final order by FDA deciding a food additive petition. *See* 21 U.S.C. § 348(g)(1) ("[A]ny person who will be adversely affected by [an order deciding a food additive petition] may obtain judicial review . . . in the [appropriate] United States Court of Appeals."); *In re Nat. Res. Def. Council*, 645 F.3d 400, 407 (D.C. Cir. 2011) ("[E]xclusive jurisdiction over challenges relating to properly submitted food additive petitions will be in the courts of appeals."). "The All Writs Act . . . authorizes [this Court] to issue mandamus relief necessary to protect [its] 'prospective jurisdiction.'" *Cal. Power Exch. Corp. v. Fed. Energy Regulatory Comm'n*, 245 F.3d 1110, 1119 (9th Cir. 2001) (quoting *Pub. Util. Comm'r v. Bonneville Power Admin.*, 767 F.2d 622, 630 (9th Cir. 1985)); *see also* 28 U.S.C. § 1651 (authorizing federal courts to issue all writs appropriate "in aid of their respective jurisdictions"); *Fed. Trade Comm'n v. Dean Foods Co.*, 384 U.S. 597, 603 (1966) ("The exercise of . . . power [under the All Writs Act] extends to

the potential jurisdiction of the appellate court where an appeal is not then pending but may later be perfected.") (citation omitted).

Petitioners Breast Cancer Prevention Partners and Center for Environmental Health have their principal places of business in this Circuit. As a result, this Circuit would have jurisdiction to review their challenge to a final order by FDA deciding the Petition. *See* 21 U.S.C. § 348(g) (authorizing review in the Court of Appeals "wherein [petitioner] . . . has [its] principal place of business").[2] Therefore, this Court has jurisdiction to determine whether FDA has unlawfully withheld its decision on the Petition and to compel FDA to act.[3] *See A Community Voice v. U.S. Envtl. Prot. Agency*, 878 F.3d 779, 783 (9th Cir. 2017) (finding that the Ninth Circuit's jurisdiction to consider a petition for writ of mandamus "is dependent on [its] jurisdiction to review a final rule.") [hereinafter *Community*].

ISSUE PRESENTED

Whether mandamus is warranted here, where: (1) FDA has unlawfully withheld agency action by failing to issue a responsive regulation or deny

[2] In addition, Petitioners collectively have millions of members, many of whom live within this Court's jurisdiction.

[3] "[T]he clear weight of federal authority holds that venue is proper in a multi-plaintiff case if *any* plaintiff resides in the District." *CAlifornians for Renewable Energy v. U.S. Envtl. Prot. Agency*, No. C 15-3292 SBA, 2018 WL 1586211, at *5 (N.D. Cal. Mar. 30, 2018) (refusing to dismiss claims brought by co-plaintiffs residing outside the relevant judicial district and collecting cases in support).

Petitioners' properly submitted food additive petition, despite a statutory mandate that FDA decide food additive petitions within at most 180 days of the filing date—in this case, by August 8, 2016—and (2) Petitioners' only available remedy is an order from this Court compelling FDA to act.

STATEMENT OF THE CASE

I. Legal Framework

The Food Act directs FDA to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2). Faced with the food industry's increasing use of untested chemicals, Congress expanded upon this general requirement in 1958 by amending the statute to "prohibit the use in food of additives which have not been adequately tested to establish their safety." Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784, 1784 (1958). Congress defined the phrase "food additive" broadly to include "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s).[4]

[4] In addition to certain exceptions not relevant here, a substance is not a food additive if it is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use." *Id.* § 321(s). Substances within this exception are commonly referred to as "generally recognized as safe" or "GRAS." The interplay between food additives

A food additive is "deemed to be unsafe" unless used in conformity with a regulation prescribing the conditions under which the additive may be safely used. *Id*. § 348(a).[5] By mandating that the proposed use of a food additive affirmatively be found "safe," Congress intended to "require[] proof of a reasonable certainty that no harm will result from [the additive's] use." H.R. Rep. No. 85-2284, at 4 (1958); S. Rep. No. 85-2422, at 6 (1958), *reprinted* in 1958 U.S.C.C.A.N. 5300, 5305. FDA maintains a list of approved flavoring substances and adjuvants, along with conditions for their safe use, at 21 C.F.R. § 172.515.[6]

The Food Act expressly provides that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." 21 U.S.C. § 348(c)(3)(A). This prohibition on carcinogenic additives, known as the Delaney Clause, is absolute.

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and GRAS substances is discussed below. *See infra* note 16.

[5] In limited circumstances, the Food Act permits FDA to allow "investigational use [of unapproved food additives] by qualified experts," provided this use "is consistent with the public health." *Id.* § 348(j). The investigational use of food additives is not at issue here.

[6] Within the meaning of FDA's food additive regulations, "[f]lavoring agents and adjuvants" are "[s]ubstances added to impart or help impart a taste or aroma in food." 21 C.F.R. § 170.3(o)(12). An "adjuvant" is "[a]n ingredient that affects the food product and/or aids in the perception of the flavor." Dolf De Rovira, Sr., Dictionary of Flavors 6 (3d. ed. 2017).

As this Court has recognized, "the language of the Delaney clause, its history and purpose all reflect that Congress intended [FDA] to prohibit all additives that are carcinogens, regardless of the degree of risk involved."[7] *Les v. Reilly*, 968 F.2d 985, 986 (9th Cir. 1992); *see id.* at 988 ("[T]he Delaney Clause . . . affords no flexibility once FDA scientists determine that [its] conditions are satisfied. A food additive that has been found in an appropriate test to induce cancer in laboratory animals may not be approved for use in food for any purpose, at any level, regardless of any 'benefits' that it might provide." (quoting Richard A. Merrill & Peter Barton Hutt, Food and Drug Law: Cases and Materials, 78 (1980))).[8]

Under the Food Act, any person may submit a petition to FDA "proposing the issuance of a regulation prescribing the conditions under which [a food] additive may be safely used." 21 U.S.C. § 348(b)(1); *see also* 21 C.F.R. § 171.1. The Food Act sets forth substantive and procedural requirements for food additive petitions seeking approval of new food additives and, as is relevant here, mandates

[7] The U.S. Environmental Protection Agency ("EPA") has authority to regulate pesticide tolerances under the Food Act, while FDA regulates all food additives other than pesticides. *See* 5 U.S.C.A. App. 1 Reorg. Plan 3 1970. Because FDA is the agency most often required to implement the Delaney Clause, the *Les* court refers to FDA scientists instead of EPA scientists. And given that the Delaney Clause limits the regulatory authority of both agencies, the court's discussion applies with equal force to EPA and FDA.

[8] "FDA interprets the Delaney Clause as applying to food additives established prior to any indication of carcinogenic effect for such chemicals." *California ex rel. Can de Kamp v. Reilly*, 750 F. Supp. 433, 438 (E.D. Cal. 1990).

that food additive petitions seeking amendment or repeal of existing regulations "shall conform to the [statutory] procedure . . . for the promulgation of [new] regulations." 21 U.S.C. § 348(i); *see also id.* § 348(b), 348(c); *Nat. Res. Def. Council*, 645 F.3d at 403 ("[A] petitioner submitting new data to support the amendment or repeal of a regulation must do so through a food additive petition."). FDA shall not issue a regulation allowing use of a substance in response to a food additive petition "if a fair evaluation of the data before the Secretary . . . fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe." 21 U.S.C § 348(c)(3).

Once FDA files a food additive petition, FDA has 90 days in which it must either "by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing . . . the conditions under which [the food] additive may be safely used . . . or . . . by order deny the petition." 21 U.S.C. § 348(c)(1)–(2); 21 C.F.R. § 171.100(a). In either case, FDA must "notify the petitioner of such order and the reasons for such action." 21 U.S.C. § 348(c)(1)(A); 21 C.F.R. § 171.100(a). By written notice to the petitioner, FDA may extend the period for review by 90 days. 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100(c). But under no circumstances may FDA withhold its decision on a petition for more than

180 days after filing.[9] *Id*. Thus, upon filing a petition, FDA incurs a mandatory obligation to either issue a regulation or deny the petition within 180 days.

II. FDA Approved the Use of the Seven Flavors at Issue More than Fifty Years Ago, and Food Manufacturers Continue to Use These Flavors in Common Foods.

In 1964, FDA determined that dozens of synthetic flavors were safe for use in food. *See* Synthetic Flavoring Substances and Adjuvants, 29 Fed. Reg. 14,625 (Oct. 27, 1964) (codified at 21 C.F.R. pt. 121). This determination included six of the seven flavors here at issue: benzophenone (also known as diphenylketone), ethyl acrylate, eugenyl methyl ether (also known as 4-allylveratrole, methyl eugenol, or methyleugenol), myrcene (also known as 7-methyl-3-methylene-1,6-octadiene), pulegone (also known as *p*-menth-4(8)-en-3-one), and pyridine. *Id*. In 1967, FDA approved styrene, the seventh flavor at issue. *See* Synthetic Flavoring Substances and Adjuvants, 32 Fed. Reg. 7946 (June 2, 1967) (codified at 21 C.F.R. pt. 121). Through regulation, FDA authorizes use of these flavors "in the minimum quantity required to produce their intended effect, and otherwise

[9] After a food additive petition has been filed, the petitioner may submit supplemental information in support of that petition. 21 C.F.R. § 171.6. If FDA determines that this supplemental information amounts to a substantive amendment of the petition, it will establish a new filing date, using the date on which it received the supplemental information. *Id.* But even in the event of a substantive amendment, FDA cannot extend its timeline for taking action on the petition beyond 180 days of this new, final filing date. 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100(b).

[subject to] the principles of good manufacturing practice." 21 C.F.R. § 172.515(a).

Thus, with FDA's approval, food manufacturers have used these seven flavors in food for more than half a century.[10] And, although FDA generally requires manufacturers to list the ingredients used in food on product labels, *see* 21 C.F.R. § 101.4, manufacturers need not disclose the chemical identity of all flavors used. *See id.* § 101.4(b)(1) (excepting flavors from the requirement that "[t]he name of an ingredient [declared on food labeling] shall be a specific name and not a collective (generic) name"). Instead, FDA permits manufacturers to indicate simply that a product contains "artificial flavors" or "natural flavors"

[10] Soon after FDA approved these flavors, the Flavor and Extract Manufacturers Association ("FEMA") determined under a different provision of the Food Act that certain uses of the flavors are "generally recognized as safe" or "GRAS," and thus allowed in food. *See* Richard L. Hall & Bernard L. Oser, *Recent Progress in the Consideration of Flavoring Ingredients under the Food Additives Amendment: 3. GRAS Substances*, 19 Food Tech. 151 (1965) (determining uses of benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine to be GRAS); Richard L. Hall & Bernard L. Oser, *Recent Progress in the Consideration of Flavoring Ingredients under the Food Additives Amendment: 4. GRAS Substances*. 24 Food Tech. 25 (1970) (determining uses of styrene to be GRAS); *but see* Samuel M. Cohen et al., Flavor & Extract Mfrs. Ass'n, *GRAS Flavoring Substances 28* 3 (2017), https://www.femaflavor.org/sites/default/files/2017-12/fema_gras_28_20171208.pdf (removing methyl eugenol—also known as eugenyl methyl ether—from the FEMA GRAS list); Samuel M. Cohen et al., *GRAS 27 Flavoring Substances*, 69 Food Tech. 41, 46 (2015), https://www.femaflavor.org/sites/default/files/27.%20GRAS.pdf (removing styrene from the FEMA GRAS list). That determination is not relevant here, except as discussed *infra* at note 17.

without identifying the specific flavors. *See id.* § 101.22. As a result, consumers have no way of knowing whether any given product contains flavors that pose a risk to their health or that they might otherwise prefer to avoid.

Although the precise flavors used in brand name products are kept secret from the public, there is no question that the seven flavors here at issue have been used—and continue to be approved for use—in food. Prominent scientific bodies, including the International Agency for Research on Cancer ("IARC")—a division of the World Health Organization—and the European Food Safety Authority's Scientific Panel on Food Additives and Flavorings, have collected substantial evidence that manufacturers add these flavors to many common foods. Food manufacturers use benzophenone, methyleugenol, and pulegone, for example, to add floral, cinnamon, and mint notes, respectively, to baked goods, beverages, candy, chewing gum, and ice cream. Decl. of Tom Neltner ¶¶ 27, 30 (sworn to on Apr. 29, 2018) ("Neltner Decl."). One chemical company touts myrcene for its ability to lend a "picnic inspired . . . slight citrus, fruity mango note" or a "sweet woody note" to beer and other beverages. *Id.* ¶ 32. Ethyl acrylate, in turn, is advertised for its "irritating brown ethereal character reminiscent of ripe pineapple, rum and whiskey, roasted onion and garlic," flavor notes which are apparently well suited to alcoholic beverages, butterscotch, and savory dishes. *Id.* Myrcene and ethyl acrylate are also used in baked goods, beverages, and candy, among other

products. *Id.* ¶ 27.[11] Many of the foods for which these flavors are marketed are widely consumed in the United States. For example, all seven of the flavors may be used in baked goods and frozen dairy products such as ice creams. *Id.* ¶ 27. Approximately 87 percent of Americans consume baked goods, such as breads, rolls, and muffins. EPA, EPA/600/R-09/052F, Exposure Factors Handbook: 2011 Edition 12-26 tbl. 12-17 (2011), https://www.epa.gov/ sites/production/files/2015-09/documents/techoverview_efh-complete.pdf. About 17 percent of Americans consume ice cream an average of every other day. Helen Smiciklas-Wright et al., U.S. Dep't of Agric., NFS Report No. 96-5, Foods Commonly Eaten in the United States at 66 (2002), https://www.ars.usda.gov/ ARSUserFiles/80400530/pdf/Portion.pdf.

Given FDA's approval of these cancer-causing flavors, there is very little consumers can do to protect themselves. As explained above, food labels do not indicate whether a product contains any of the seven flavors here at issue. And the degree of risk associated with consumption is impossible to predict; even within the broad categories of foods most likely to contain these flavors, concentrations of the flavors—and, therefore, the health consequences of ingestion—may vary

[11] Pyridine lends fishy, sour notes to baked goods, beverages, candy, and ice cream. Neltner Decl. ¶¶ 27, 30, 31. Although styrene's flavor profile is somewhat harder to identify, this flavor may be used in baked goods, candy, and ice cream. *Id.* ¶ 27.

significantly between brands. Neltner Decl. ¶ 33. Low-income communities of color may be especially at risk, because they often lack access to fresh produce and thus disproportionately rely on packaged foods. *See* Decl. of Adrienne Hollis ¶ 6 (sworn to on Apr. 26, 2018) ("Hollis Decl."). Children are also especially vulnerable, because they are among the most likely to consume processed sweets and they are rarely in a position to make their own, informed choices about which foods to eat. *See* Decl. of Nancy Buermeyer ¶ 12 (sworn to on Apr. 23, 2018) ("Buermeyer Decl.").

III. Reliable Evidence Now Shows that the Seven Flavors Induce Cancer in Humans or Animals.

In the decades following FDA's decisions to approve the seven flavors here at issue, and while industry has continuously been permitted to add the flavors to food, multiple scientific authorities determined that these flavors induce cancer in humans or animals. For instance, the U.S. Department of Health and Human Services' National Toxicology Program ("NTP")—created, in part, to "provide information about potentially toxic chemicals to health, regulatory, and research agencies" like FDA, *see About NTP*, NTP, https://ntp.niehs.nih.gov/about/ (last updated Feb. 13, 2018)—concluded that all seven flavors cause cancer in animals,

and that methyleugenol and styrene are also "reasonably anticipated to be human carcinogens." *See* Neltner Decl. ¶¶ 14,17,21.[12]

NTP's procedures for assessing carcinogenicity are "appropriate for the evaluation of the safety of food additives" and thus, NTP's conclusions are sufficient to establish carcinogenicity under the Delaney Clause. 21 U.S.C. § 348(c)(3)(A). Indeed, the studies on which NTP relied to determine that the seven flavors cause cancer are consistent with, and sometimes exceed, FDA's own toxicological principles for the safety assessment of food ingredients. Neltner Decl. ¶¶ 11, 12. The National Academy of Science has declared the testing guidelines that NTP used to establish the carcinogenicity of benzophenone, ethyl acrylate, methyleugenol, myrcene, pulegone, and pyridine to be "the gold standard for carcinogenicity testing." Nat'l Research Council, Toxicity Testing in the 21st Century: A Vision and a Strategy 22 (2007). And NTP has consistently included styrene in its congressionally-mandated Report on Carcinogens since 2011. Neltner Decl. ¶ 21.

[12] In 1998, in response to a petition from an association of chemical manufacturers, NTP withdrew its conclusion that ethyl acrylate is reasonably anticipated to be a human carcinogen, citing questions about whether studies finding that ethyl acrylate caused cancer in animals were relevant to humans. Neltner Decl. ¶ 24. Nonetheless, the following year, IARC found that these same studies provided sufficient evidence of ethyl acrylate's status as an animal carcinogen to support its conclusion that ethyl acrylate is possibly carcinogenic to humans. *Id*.

In reliance on NTP's studies and other available data, IARC also found evidence that the seven flavors cause cancer in animals and are "possibly carcinogenic to humans" or are "probably carcinogenic to humans." Neltner Decl. ¶ 22. The State of California's Office of Environmental Health Hazard Assessment ("OEHHA") has also listed all seven flavors as carcinogens based on the NTP research and results, as well as other studies. *Id.* ¶ 23.

IV. Petitioners' Food Additive Petition and FDA's Failure to Act in Response.

On July 28, 2015, Petitioners Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Working Group, and Natural Resources Defense Council, Inc., along with others, submitted the Petition to FDA, requesting *inter alia* that the agency "remove its approval of [the seven flavors] from 21 C.F.R. § 172.515 because they are not safe for use in food pursuant to the Delaney Clause." *See* Letter from Laura MacCleery, Ctr. for Sci. in the Pub. Interest, et al. to Dennis Keefe, FDA 1 (July 28, 2015), attached hereto as Exhibit 1.[13] Petitioners Environmental Defense Fund, Breast Cancer Prevention Partners (then known as Breast Cancer Fund), and WE ACT for Environmental Justice later joined the Petition. *See* Letter from Erik D. Olson,

[13] The Petition also requested that FDA "establish a zero tolerance [standard] . . . for the use of these seven flavors." Ex. 1 at 1. Petitioners are no longer pursuing this aspect of the Petition.

Nat. Res. Def. Council, et al. to Judith K. Rabaglia, FDA 1 (Oct. 24, 2015), attached hereto as Exhibit 2; Letter from Erik D. Olson, Nat. Res. Def. Council, et al. to Judith K. Rabaglia, FDA 1 (Feb. 6, 2016), attached hereto as Exhibit 3; Letter from Tom Neltner, Envtl. Def. Fund to Judith Rabaglia, FDA 1 (Apr. 3, 2018), attached hereto as Exhibit 4.

The Petition alleged that, in the years after these seven flavors were approved for use in food, "[e]ach has been found by [NTP] to induce cancer in man or animal using tests done consistent with FDA's guidance for toxicology studies for food ingredients." Ex. 1 at 1. Consequently, the Petition requested that FDA revoke its approval of these seven flavors "because they are not safe for use in food pursuant to the Delaney Clause." *Id.*

FDA initially filed the Petition on August 17, 2015. *See* Filing of Food Additive Petition, 81 Fed. Reg. 42 (Jan. 4, 2016). After filing the Petition, FDA requested that Petitioners conduct an exhaustive literature review. Ex. 5 at 1. Upon receiving the results of that review on February 10, 2016, *see* Ex. 6, FDA deemed the Petition substantively amended and set a new filing date, thereby resetting the statutory timeline for rendering a decision on the Petition. Ex. 7. Therefore, FDA had a statutory obligation to promulgate a regulation or issue a denial within 180 days of February 10, 2016—that is, by August 8, 2016 at the latest. *See* E-mail from Judy Kidwell, FDA, to Tom Neltner, Envtl. Def. Fund

(July 7, 2016) (confirming that the statutory deadline for FDA's final decision on the Petition was August 8, 2016), attached hereto as Exhibit 8. August 2016 has long since come and gone, and FDA still has not decided the Petition.

SUMMARY OF THE ARGUMENT

The objective of the Food Act is to protect consumers from unsafe food. It unambiguously and absolutely prohibits the intentional use in food of any additive that has been found to induce cancer in humans or animals. In an effort to protect the public from exposure to known carcinogens in food, Petitioners filed a food additive petition requesting removal of FDA's approval of seven synthetic flavors shown to induce cancer in humans or animals. To date, FDA has unlawfully failed to take final action in response.

FDA has a statutory obligation either to promulgate a regulation or to deny a food additive petition within 180 days of its filing date. FDA failed to do either in response to the Petition. Instead, without explanation, FDA unlawfully withheld agency action—despite the "gold-standard" studies and other information Petitioners provided showing that the seven flavors cause cancer and, thus, must be prohibited from use in food. As a result of FDA's unlawful failure to act, consumers will continue to face an ongoing risk of exposure to these carcinogenic flavors for as long as the food industry continues to use them in food. There are no administrative remedies available to Petitioners to compel agency action. Thus, a

writ of mandamus is necessary and appropriate to require FDA to follow the law and decide the underlying Petition.

STANDING

Petitioners have both organizational and associational standing to pursue this writ of mandamus.

Organizational Standing

Organizational standing requires a showing of "both a diversion of resources and frustration of mission." *Fair Housing Council v. Roommate.com, LLC*, 666 F.3d 1216, 1219 (9th Cir. 2012) (internal quotation marks omitted); *see also Valle Del Sol Inc. v. Whiting*, 732 F.3d 1006, 1018 (9th Cir. 2013) (same); *Smith v. Pac. Props. & Dev. Corp.*, 358 F.3d 1097, 1105 (9th Cir. 2004) (same). Petitioners easily satisfy these requirements.

Protecting public health by advocating for safer food is a fundamental component of each Petitioner's mission. For example, Petitioner Breast Cancer Prevention Partners ("BCPP") works to prevent breast cancer and other cancers, in part, by eliminating exposure to toxic chemicals. Buermeyer Decl. ¶ 2. For more than a decade, this work has included efforts "to prevent chemicals linked to cancer from being used in food and food packaging." *Id.* ¶ 9. Petitioner Center for Environmental Health ("CEH") also works "to remove toxic chemicals from food and food packaging." Decl. of Caroline Cox ¶ 7 (sworn to on Apr. 24, 2018)

("Cox Decl."); *see also* Decl. Melanie Benesh ¶¶ 2, 5 (sworn to on May 1, 2018) ("Benesh Decl."); Hollis Decl. ¶ 3; Decl. of Andrew Kimbrell ¶ 3 (sworn to on Apr. 2, 2018) ("Kimbrell Decl."); Decl. of Lisa Y. Lefferts ¶ 2 (sworn to on Apr. 27, 2018) ("Lefferts Decl."); Neltner Decl. ¶ 2; Decl. of Gina Trujillo ¶ 7 (sworn to on Apr. 6, 2018).

The food additive petition process is a critical tool that allows Petitioners to advance their missions. *See, e.g.*, Cox Decl. ¶ 9 (CEH joined the Petition "because [it] aligns directly with our mission [of] protect[ing] people from toxic chemicals."). FDA's unlawful failure to decide the Petition by the statutory deadline frustrates Petitioners' ability to achieve these missions. *See, e.g.*, Buermeyer Decl. ¶ 13 ("FDA's failure to decide the Petition inhibits BCPP's ability to carry out our mission."); Lefferts Decl. ¶ 9 ("FDA's failure to decide the Petition by the statutory deadline frustrates CSPI's ability to achieve its goals."). It also eliminates, or at least renders ineffective, an important and powerful mechanism to advance food safety. *See, e.g.*, Benesh Decl. ¶ 12 ("The food additive petition process is the most efficient mechanism to eliminate dangerous chemicals from food [but,] because EWG cannot rely on FDA to comply with the statutory deadlines that govern the food additive petition process, we must also pursue alternative methods of eliminating dangerous chemicals."); Neltner Decl. ¶ 6 (explaining that the food additive process is useful, in part, because it "imposes

a mandatory deadline by which FDA must decide either to issue a regulation in response to a food additive petition or to deny the petition").

In addition to frustrating Petitioners' public health missions, FDA's failure to decide the Petition impedes Petitioners' ability to educate their members and the public about the risks of exposure to harmful chemicals in food. Public education is a primary focus of each Petitioner. For example, BCPP concentrates, in part, on "educat[ing] the public about chemicals that have been linked to cancer—many of which are found in food and everyday consumer products—and the simple steps that people can take to reduce their risk." Buermeyer Decl. ¶ 5. "EWG works hard to provide [its] supporters and other consumers with reliable information about nutrition and food safety." Benesh Decl. ¶ 6; *accord* Cox Decl. ¶ 2 (CEH relies on "public education," among other strategies, to achieve its goal); Lefferts Decl. ¶ 2 (CSPI works "to provide consumers with current, useful information about health, nutrition, and well-being").

Since the Food Act requires FDA to explain its decision on any food additive petition, the Agency's unlawful failure to issue a decision also deprives Petitioners of valuable information that they could use to inform their members and the public about future exposure to the flavors here at issue, as well as FDA's treatment of science related to these and other cancer-causing chemicals. *See, e.g.*, Buermeyer Decl. ¶ 14 ("If FDA were to deny the Petition, BCPP would receive

valuable information."); Cox Decl. ¶ 12 ("Because [CEH] do[es] so much work involving food, it would be valuable for us to have more information about how FDA evaluates science."); Lefferts Decl. ¶ 9 ("If FDA were to deny the Petition, it would have to explain why—and its reasons could be instructive for our efforts to remove other carcinogenic substances from the food supply, which would make CSPI more effective overall."); Neltner Decl. ¶ 8 ("EDF could use [the] information [provided by FDA along with a decision to deny the Petition] as a roadmap for future food additive petitions, to help us work more efficiently.").

Not only does FDA's failure to decide the Petition injure Petitioners' missions, but it likewise has forced Petitioners to divert time and resources from other important priorities. Because Petitioners cannot rely on the food additive petition process given FDA's failure to comply with the Food Act's mandatory deadlines, Petitioners must pursue alternative methods to protect their members and the public from these flavors and other unsafe food additives. *See, e.g.*, Buermeyer Decl. ¶ 16 ("We have . . . been working with our coalition partners to explore other ways to keep food safe, given that FDA's adherence to the food additive petition process is unreliable."); Lefferts Decl. ¶ 9 (CSPI has "invested time and resources in evaluating other strategies to eliminate exposures to toxic chemicals and carcinogens, such as market campaigns."). These alternative strategies are often more expensive and less effective. *See, e.g.*, Cox Decl. ¶ 12

("Because FDA delayed its decision on the Petition and routinely falls short of its mandate to protect the public from unsafe food," CEH has begun pursuing other, less efficient strategies to protect people from carcinogenic additives). Therefore, FDA's failure to decide the Petition has compelled Petitioners to "divert[] time and attention from other important projects" they otherwise would pursue. Buermeyer Decl. ¶ 15; *see* Cox Decl. ¶ 12 (same); Benesh Decl. ¶ 12 (same).

For these reasons, Petitioners have organizational standing to bring this action.

Associational Standing

To establish standing to sue on behalf of its members, an association must show three things: *first*, that the interests it seeks to protect are germane to the association's purpose; *second*, that neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit; and *third*, that the association's members would have standing to sue in their own right. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977), *superseded by statute on other grounds*; *accord Columbia Basin Apartment Ass'n v. City of Pasco*, 268 F.3d 791, 798 (9th Cir. 2001). "[T]he presence in a suit of even one party with standing suffices to make a claim justiciable." *Mont. Shooting Sports Ass'n v. Holder*, 727 F.3d 975, 981 (9th Cir. 2013) (internal citation and

quotation marks omitted); *accord Rumsfeld v. Forum for Academic & Inst'l Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006).

Petitioners clearly satisfy this test. *First*, Petitioners filed this petition for mandamus to protect the health of their members and the public at large by reducing their exposure to certain carcinogenic flavors, and protection of public health is an interest germane to each association's purpose. *See, e.g.*, Lefferts Decl. ¶ 7 ("CSPI joined [the] Petition . . . because eliminating the use of these flavors will help to protect all consumers, including CSPI's supporters."); *see also Pub. Citizen v. Dep't of Transp.*, 316 F.3d 1002, 1019 (9th Cir. 2003), *rev'd on other grounds*, 541 U.S. 752 (2004) (concluding that associations had standing, in part, because the "potential adverse health consequences" at issue were pertinent to the interests of associations "concerned with the physical well-being of their membership"). *Second*, this lawsuit does not require the participation of Petitioners' individual members because neither the claims asserted nor the relief sought requires individualized proof. *See id.* (finding "no indication that resolving [a procedural challenge] would require, or even be assisted by the participation of [an association's] individual members"). *Third*, as discussed below, Petitioners' members would have standing to sue in their own right.

To demonstrate that their members would have standing to sue in their own right, Petitioners must satisfy another three-part test: *first*, they have suffered an

injury in fact; *second*, that injury is traceable to FDA's action; and *third*, the injury is likely to be redressed by a favorable judicial decision. *See Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969 (9th Cir. 2003). In this case, where FDA has violated a procedural duty, the injury-in-fact prong is measured by whether (a) FDA violated procedural rules that (b) are designed to protect concrete interests of Petitioners' members, and (c) it is reasonably probable that FDA's unlawful failure to act will threaten the concrete interests of Petitioners' members.[14] *See Ctr. for Food Safety v. Vilsack*, 636 F.3d 1166, 1171 (9th Cir. 2011) (setting forth the three-part test for establishing procedural injury).

Petitioners satisfy this test as well:

(a) FDA unquestionably violated the statutory and regulatory requirement that it decide each food additive petition within 180 days after its filing. *See* 21 U.S.C. § 348(c)(2), 348(i); 21 C.F.R. § 171.100.

(b) This requirement to act promptly on questions of food safety protects the concrete interests that Petitioners' members have in protecting themselves and their families from exposure to unsafe substances in their food. *See, e.g.*, 21 U.S.C. § 348(c)(3)(A); *see also Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001)

[14] Injury-in-fact "may be alleged as a 'procedural' injury or a 'substantive' injury. Procedural injury results from the violation of a statute or regulation that guarantees a particular *procedure*. In contrast, a substantive injury results from the violation of a statute or regulation that guarantees a particular *result*." *CAlifornians for Renewable Energy*, 2018 WL 1586211, at *7 (internal citations omitted).

("[E]vidence of a credible threat to the plaintiff's physical well-being [that could result from an agency's violation of a procedural requirement] falls well within the range of injuries to cognizable interests that may confer standing."); *see also* Decl. of Jean Bissell ¶ 4 (sworn to on Apr. 27, 2018) ("Bissell Decl.") ("I would like to be able to choose from the array of foods that are available at my grocery store, without putting myself and my family at risk of exposure to hidden cancer-causing flavors or other dangerous chemicals."); Decl. of Hendy Dayton ¶ 5 (sworn to on Apr. 29, 2018) ("Dayton Decl.") ("I think carefully about the food I eat and I try to make healthy choices for my family."); Decl. of Tina Eshaghpour ¶ 10 (sworn to on Apr. 10, 2018) ("If another living being has been harmed by a chemical, I don't want to put that chemical into my body—and I don't want to give it to my children to consume.").

(c) FDA's unlawful failure to act threatens the health of Petitioners' members because those members now continue to risk consuming foods that could lawfully contain flavors known to induce cancer and, thus, could face an increased threat of developing cancer as a result.[15] *See Nat. Res. Def. Council v. EPA*, 735

[15] It is reasonably probable that FDA's unlawful inaction will threaten the health of Petitioners' members, even though FDA's approval of the carcinogenic flavors permits—but does not require—manufacturers to use these flavors in food. *See Citizens for Better Forestry*, 341 F.3d at 973 (finding a reasonable probability that a new national forest plan would threaten plaintiffs' interests in enjoying national

F.3d 873 (9th Cir. 2013) (finding standing where agency action "increase[d] the threat of future harm" to group's members, and explaining "[w]e have consistently held that an injury is 'actual or imminent' where there is a 'credible threat' that a probabilistic harm will materialize."); *see also* Decl. of Castedy Castro ¶ 10 (sworn to on Apr. 26, 2018) ("Castro Decl.") ("I'm sure I will eat food containing some of these flavors again in the future and I'm afraid that I might be at risk of developing cancer as a result."); Dayton Decl. ¶¶ 7, 9 ("I work full-time, so I buy packaged foods for convenience. . . . I generally don't buy foods with artificial flavors[] [b]ut, for things like candy, cookies, ice cream, or cereal, I don't pay as much attention. . . . I will keep buying packaged baked goods, candy, cookies, and ice cream with artificial flavor. . . . [A]rtificial flavors are so ubiquitous; I'm sure that I would end up consuming them inadvertently even if I tried to avoid them."); Eshaghpour Decl. ¶¶ 8, 9, 11 ("I wish I could assume that packaged foods were fully vetted for safety before arriving on store shelves — but I know better. . . . I don't have time to make everything that my family eats from scratch, so I'll continue to risk exposure to the cancer-causing flavors at issue. . . . I try to be careful, but I don't think I can protect myself and my family from consuming foods that contain those flavors."). The risk of exposure to cancer-causing flavors is

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forests, even though the plan had no direct effect on forests but, instead, merely reduced environmental protections).

certain, given that manufacturers can freely use these flavors in food. *See supra* Section II. And Petitioners' members have no way of protecting themselves from exposure because FDA does not require food manufacturers to indicate whether their products contain the carcinogenic flavors at issue. *See, e.g.*, Decl. of Rolf Bandle ¶ 6 (sworn to on Apr. 5, 2018) ("It is impossible for me to fully avoid specific flavors that aren't identified on food labels."); Decl. of Anne H. Barker ¶ 9 (sworn to on Apr. 4, 2018) (The lack of clear labeling requirements "makes it impossible to fully protect myself from these harmful additives when eating out or at home."); Decl. of Maria Juur ¶ 10 (sworn to on Mar. 30, 2018) (Because manufacturers need not identify particular flavoring ingredients on food packaging, "I . . . have no way of knowing whether any given product contains flavors that pose a risk to my health or that I might otherwise prefer to avoid."). Even if manufacturers were required to identify these and other flavors on ingredient panels, Petitioners' members would still risk exposure because many people lack the time to review ingredient panels or the money to purchase specialty products made without chemical additives. *See, e.g.*, Castro Decl. ¶ 9 ("If [my mom and I] tried to buy only natural food [without artificial flavor], it would take a lot of time and it would probably be too expensive.")).[16]

[16] "For purposes of procedural injury, [p]laintiffs are not required to demonstrate that the EPA's procedural compliance would have ultimately afforded them relief

Given that Petitioners' members clearly have suffered a cognizable procedural injury, they need not meet all the usual requirements for traceability and redressability under the general test for standing. *See Ctr. for Food Safety*, 636 F.3d at 1171 n.6 (A party "seeking to enforce procedures that [affect their] concrete interests may do so 'without meeting all the normal standards for redressability and immediacy.'" (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009)). Instead, Petitioners "must show only that they have a procedural right that, if exercised, *could* protect their concrete interests." *WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1154 (9th Cir. 2015) (quoting *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1226 (9th Cir. 2008)). Petitioners' members satisfy this standard because, regardless of how FDA acts on the Petition, Petitioners' interests will be advanced. If FDA were to revoke its approval of the carcinogenic flavors at issue, it would safeguard Petitioners' members' concrete interests in protecting themselves and their families from exposure to these carcinogens. *See, e.g.*, Hollis Decl. ¶ 10 ("If FDA were to issue a regulation revoking its approval of the flavors at issue in this litigation, that

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. . . Rather, 'a litigant need only demonstrate that he has a procedural right that, if exercised, *could* protect his concrete interests and that those interests fall within the zone of interests protected by the statute at issue.'" *CAlifornians for Renewable Energy*, 2018 WL 1586211 at *8 (quoting *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1082–83 (9th Cir. 2015)). As discussed *supra*, Petitioners satisfy this showing.

would be very beneficial for WE ACT's members, because it would eliminate one route of exposure to these dangerous chemicals."). Second, if FDA were to deny the Petition, Petitioners could file objections and, if necessary, seek judicial review. *See* 21 U.S.C. § 348(f), (g). If Petitioners prevail before the agency or in court, their success would lead to the revocation of approval for the carcinogenic additives, thus ensuring a safer food supply for their members and the public at large.[17]

ARGUMENT

This case presents the type of extraordinary circumstances that warrant a writ of mandamus. Under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), and the Food Act, 21 U.S.C. § 348, FDA has unlawfully withheld action

[17] As explained above, *see supra* note 10, FEMA has independently determined certain uses of these flavors to be "generally recognized as safe" ("GRAS"). Consequently, FDA may argue that this Court cannot redress the injury suffered by Petitioners' members because—even if FDA were to revoke its approval of these flavors—manufacturers could continue to use them under the GRAS system and thus, Petitioners' members might continue to be exposed. This is incorrect. If a substance does not qualify as "safe" for the purpose of FDA approval as an additive, it cannot be "safe" under the GRAS system. GRAS substances and food additives are held to the same standard of safety. *See id.* § 321(u) (explaining the meaning of the term "safe" as applied in 21 U.S.C. §§ 321(s) and 348); 21 C.F.R. § 570.30(b) ("General recognition of safety shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive."). Thus, the Food Act's prohibition on cancer-causing additives being deemed safe applies with equal force to GRAS determinations. No substance can be generally recognized as safe if it has been found to induce cancer—and, thus, deemed unsafe—under the Delaney Clause.

on the Petition, denying Petitioners a decision on the Petition for more than eighteen months beyond the date when FDA's decision was due. This failure to act is unreasonable and unjustifiable given the clear and certain nature of the relevant law. The Food Act leaves no doubt that FDA had at most 180 days to rule on the Petition. But FDA failed to do so. And the statute likewise makes clear that FDA lacks discretion to deem "safe" any food additive found to induce cancer in humans or animals—but, here, FDA has failed to revoke its approval of the seven flavors despite having been presented with credible scientific evidence demonstrating that these flavors are carcinogens. Every day that FDA unlawfully withholds a decision, Petitioners' members face continued risk of exposure to carcinogenic substances in their food, which jeopardizes their health and welfare. Compelling agency action is the only remedy available to redress these harms, as there are no administrative means to compel FDA to decide the Petition. Mandamus is thus necessary and appropriate to effectuate the purpose of the Food Act, to ensure that our food is free from carcinogens, to protect Petitioners' interests, and to remedy the injury to health and welfare that Petitioners' members continue to suffer.

I. FDA Unlawfully Withheld Mandatory Agency Action by Failing to Act on the Petition Within 180 Days of the Filing Date.

Under the APA, where an agency has a clear duty to take a specific action, reviewing courts can "compel agency action unlawfully withheld or unreasonably

delayed." 5 U.S.C. § 706(1); *see Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62–63 (2004). The designations "unlawfully withheld" and "unreasonably delayed" are separate and distinct: the former applies when an agency fails to meet a clear statutory deadline, whereas the latter applies when there is no mandatory timeline governing the agency action at issue. *San Francisco Baykeeper, Inc. v. Browner*, 147 F. Supp. 2d 991, 1005 (N.D. Cal. 2001) ("The prongs of [5 U.S.C. § 706(1)]—that is, 'unreasonably delayed' and 'unlawfully withheld'—are mutually exclusive."); *see also Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1177 n.11 (9th Cir. 2002) (distinguishing situations in which an agency unlawfully withheld action in violation of a statutorily-imposed, mandatory deadline from those involving "unreasonable delay in the absence of a firm deadline"); *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1190 (10th Cir. 1999) ("[T]he distinction between agency action 'unlawfully withheld' and 'unreasonably delayed' turns on whether Congress imposed a date-certain deadline on agency action.").

In this case, there can be no dispute that FDA has unlawfully withheld action: the Food Act imposes a mandatory deadline by which FDA must decide food additive petitions, *see* 21 U.S.C. § 348(c)(2), 348(i); 21 C.F.R. § 171.100, and FDA has failed to comply with that deadline, *San Francisco Baykeeper, Inc.*, 147 F. Supp. 2d at 1005 ("[A]n action is 'unlawfully withheld' if an agency fails to meet a clear deadline prescribed by Congress."); *Forest Guardians*, 174 F.3d at

1190 ("[W]hen an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action."). FDA set a February 10, 2016, filing date for the Petition, but to this day has neither issued a regulation nor denied the Petition, in clear violation of its statutory duty to do so.

II. FDA's Failure to Act Warrants Mandamus Relief.

A. A Writ of Mandamus Is Warranted to Effectuate the Purpose of the Food Act.

Mandamus is an appropriate vehicle to compel an agency to act when it has unlawfully withheld, as here, or unreasonably delayed agency action within the meaning of the APA, 5 U.S.C. § 706(1). *See*, *e.g.*, *Community*, 878 F.3d at 786 (granting mandamus compelling agency action where the agency unreasonably delayed in its "duty under the APA to fully respond to [p]etitioners' rulemaking petition"); *Pesticide Action Network v. U.S. Envtl. Prot. Agency*, 798 F.3d 809, 814 (9th Cir. 2015) (granting mandamus compelling agency action where the agency failed to complete its work in a reasonable time, as required under the APA); *In re Paralyzed Veterans of Am.*, 392 F. App'x. 858, 860 (Fed. Cir. 2010) (granting mandamus where the agency failed to take non-discretionary action by a congressionally imposed deadline and explaining that "[m]andamus is clearly the only avenue" by which petitioners can "compel [a federal agency] to cease what they allege is an unlawful agency action").

This Court applies different tests based on whether the agency has "unlawfully withheld" or "unreasonably delayed" action. It uses a balancing test to determine whether mandamus is warranted in situations in which an agency is alleged to have unreasonably delayed action under the APA. *See Community*, 878 F.3d at 783–84 ("When deciding whether to grant a mandamus petition on the grounds of unreasonable delay, this court applies the six factors balancing test set out by the D.C. Circuit in [*Telecommunications Research & Action Ctr. v. Fed. Commc'ns Comm'n* ("*TRAC*"), 750 F.2d 70, 75 (D.C. Cir. 1984)].")[18] However, if an agency has not merely delayed but, instead, has unlawfully withheld action altogether, "no balancing of factors is required or permitted." *See, e.g.*, *Badgley*, 309 F.3d at 1177 n.11; [19] *Forest Guardians*, 174 F.3d at 1190; *see also Rosario v.*

[18] Although this Court sometimes employs a "general" three-part test for mandamus, *see, e.g.*, *Cal. Power Exch. Corp.*, 245 F.3d at 1120 (using general test to analyze request to stay agency action), the general test does not apply when the underlying cause of action involves a claim of agency action unlawfully withheld or unreasonably delayed. *See id*. at 1125–26 (applying *TRAC* balancing test to mandamus petition seeking to redress agency's unreasonable delay). Accordingly, the general test for mandamus does not apply here.

[19] Though *Badgley* involved a request for an injunction rather than one for mandamus, both this Court and the U.S. Supreme Court have found those remedies to be equivalent. *See, e.g.*, *Miguel v. McCarl*, 291 U.S. 442, 452 (1934) ("The mandatory injunction here prayed for is in effect equivalent to a writ of mandamus, and is governed by like considerations."); *see also Fallini v. Hodel*, 783 F.2d 1343, 1345 (9th Cir. 1986) ("When the effect of a mandatory injunction is equivalent to the issuance of mandamus it is governed by similar considerations.").

U.S. Citizenship & Immigration Servs., No. C15-0813JLR, 2017 WL 3034447, at *9 (W.D. Wash. July 18, 2017) ("[T]he Ninth Circuit has rejected the *TRAC* standard where Congress has specifically provided a deadline for performance." (internal quotation marks and citations omitted)); *Padres Hacia una Vida Mejor v. Jackson*, 922 F. Supp. 2d 1057, 1069–70 (E.D. Cal. 2016), *aff'd sub nom. Padres Hacia una Vida Mejor v. McCarthy*, 614 F. App'x 895 (9th Cir. 2015) ("The 'unlawfully withheld' analysis does not consider the traditional *TRAC* Factors for reasonableness, rather the 'unlawfully withheld' analysis is essentially concerned with whether there is or is not compliance with a statutory command." (citing *Badgley*, 309 F.3d at 1177 n.11, 1178 and *Forest Guardians*, 174 F.3d at 1189–91) (internal footnote omitted)); *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 970–71 (N.D. Cal. 2013) ("[W]here Congress has specifically provided a deadline for performance by an agency, no balancing of factors is required or permitted." (internal quotation marks and citations omitted)); *Ctr. for Biological Diversity v. Brennan*, 571 F. Supp. 2d 1105, 1135 (N.D. Cal. 2007) (concluding, without balancing the *TRAC* factors, that judicial intervention was necessary to effectuate the purpose of a statute under which an agency had unlawfully withheld action). Instead, where "Congress has specifically provided a deadline for [agency action]," courts must compel the agency to complete that action if necessary to effectuate the purpose behind the statute. *Badgley*, 309 F.3d at 1177 & n.11.

Here, mandamus relief is warranted because a response to the Petition within the statutorily mandated time frame is necessary to effectuate the public health purposes of the Food Act. As this Court has recognized, "[t]he [Food Act] is designed to ensure the safety of the food we eat." *Les*, 968 F.2d at 986; *see also United States v. Sullivan*, 332 U.S. 689, 696 (1948) (recognizing that the Food Act "was designed primarily to protect consumers from dangerous products"); *Pub. Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987) ("The primary goal of the [Food Act] is human safety."). Consistent with this general purpose, the Delaney Clause "prohibits the use of any food additive that is found to induce cancer." *Les*, 968 F.2d at 986; *see also id.* at 989 ("[T]he legislative history [of the Delaney Clause] supports the conclusion that Congress intended to ban all carcinogenic food additives, regardless of the amount or significance of risk, as the only safe alternative.").

The Food Act's mandatory deadline for decisions on food additive petitions advances the statute's purpose by ensuring that FDA does not allow decisions implicating food safety to languish. And this deadline is counted in *days*, not months or years, thus indicating Congress's intent that FDA act promptly to protect public health. *See In re People's Mojahedin Org. of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012) [hereinafter *Mojahedin*] (explaining that "[t]he specificity and relative brevity of [a] 180-day [statutory] deadline manifests the Congress's intent that the

[agency] act promptly" and finding that the agency's "twenty-month failure to act plainly frustrates the congressional intent and cuts strongly in favor of granting [petitioner's] mandamus petition").

By unlawfully withholding action on the Petition, FDA is permitting manufacturers to continue using carcinogenic flavors in food in direct contravention of the Delaney Clause and the Food Act's central purpose. Despite the clear statutory mandate to act within 180 days of the Petition's filing date, FDA has unlawfully withheld action. A writ of mandamus is therefore warranted to compel agency action necessary to effectuate the purpose of the Food Act.

B. Even if a Balancing Test Were Appropriate Under the Circumstances, a Writ of Mandamus Is Warranted to Compel FDA to Issue a Regulation or Deny the Petition.

Where an agency has unreasonably delayed action (as opposed to unlawfully withheld action), this Court applies the six-factor balancing test set forth in *Telecommunications Research and Action Center*, 750 F.2d at 79–80, to determine whether mandamus is warranted. *See, e.g.*, *Community*, 878 F.3d at 786. However, as discussed *supra*, application of the *TRAC* factors would be inappropriate and impermissible here because "Congress has specifically provided a deadline" by which FDA must act. *See Badgley*, 309 F.3d at 1177 n.11. For the reasons set forth above, application of the proper test reveals that this Court should grant Petitioner's request for a writ of mandamus.

Nevertheless, should this Court decide that the *TRAC* test does apply, mandamus relief is still warranted. To determine whether an agency has unreasonably delayed agency action, this Court considers the six *TRAC* factors:

> (1) the time agencies take to make decisions must be governed by a rule of reason;
>
> (2) whether the relevant statute includes a timetable or other indication of the speed with which the agency is expected to act, which may supply content for this rule of reason;
>
> (3) whether human health and welfare are at stake;
>
> (4) the effect of expediting delayed action on agency activities of a higher or competing priority;
>
> (5) the nature and extent of the interests prejudiced by delay; and
>
> (6) whether there is any impropriety lurking behind agency lassitude, though no such finding is necessary to hold that agency action is unreasonably delayed.

See Community, 878 F.3d at 786 (quoting *TRAC*, 750 F.2d at 80). Consideration of the six *TRAC* factors compels a finding that FDA has unreasonably delayed in issuing a final decision on the Petition.

1. *FDA's Nearly Two-Year Delay in Deciding the Petition Is Excessive and Violates the Rule of Reason Shaped by the Food Act's 180-Day Deadline.*

Under *TRAC*, "[t]he first and most important factor is that the time agencies take to make decisions must be governed by a rule of reason." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (internal quotation marks

omitted). If the relevant statute includes "a timetable or other indication of the speed with which [Congress] expects the agency to proceed," that indication "may supply content for this rule of reason." *Community*, 878 F.3d 786 (quoting *TRAC*, 750 F.2d at 80). "[A] reasonable time for agency action is typically counted in weeks or months, not years." *Id.* at 787 (citing *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004)).

FDA's failure to decide the Petition clearly violates the rule of reason, as shaped by the Food Act's 180-day deadline. FDA filed the Petition in its final form on February 10, 2016, thus incurring an obligation to issue a final order within six months at the latest, and yet 26 months later, FDA has failed to act. This delay is unreasonable under the first two *TRAC* factors and weighs in favor of granting mandamus relief. *See Mojahedin*, 680 F.3d at 837 (concluding that an agency's "twenty-month failure to act plainly frustrates the congressional intent" underlying a 180-day statutory deadline).

2. The Health and Welfare of Millions of Individuals Exposed to the Carcinogenic Flavors Support a Finding of Unreasonable Delay.

The third *TRAC* factor further weighs in favor of an order compelling FDA to decide the Petition. "When the public health may be at stake, [an] agency must move expeditiously to consider and resolve the issues before it." *Pub. Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 34–35 (D.C. Cir. 1984); *see Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987) ("The

deference traditionally accorded to an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay."). Indeed, as the D.C. Circuit has explained in compelling an agency to act, "[t]he risk to human life need not be a certainty to justify expedition [of agency action]." *Pub. Citizen Health Research Grp. v. Auchter*, 702 F.2d 1150, 1158 n.26 (D.C. Cir. 1983).

Here, because of FDA's failure to decide the Petition within the statutory timeframe, manufacturers may continue to add the carcinogenic flavors to food and, as a result, consumers continue to risk exposure to those flavors and the concomitant increased risk of cancer. FDA's inaction is especially egregious because consumers often cannot avoid foods containing carcinogenic flavors and thus lack the ability to protect themselves. *See Cutler*, 818 F.2d at 898 ("Lack of alternative means of eliminating or reducing the hazard necessarily adds to unreasonableness of a delay.").

3. No Higher, Competing Priorities Justify FDA's Delay.

In imposing a relatively short deadline by which FDA must resolve a food additive petition, "Congress undoubtedly knew the enormous demands placed upon the [agency]." *See Mojahedin*, 680 F.3d at 837. Nonetheless, Congress mandated prompt action on food additive petitions and included express provisions for judicial review, thus emphasizing the importance of expediency when making decisions implicating food safety. Revoking approval for the use of the flavors at

issue would reduce exposure to carcinogens and thus help to lower the incidence of cancer nationwide.[20] FDA's timely action on the Petition is therefore critically important to public health, and thus the fourth *TRAC* factor weighs in favor of granting the requested relief.

4. FDA's Delay Prejudices Individuals Exposed to the Carcinogenic Flavors and Prevents Petitioners from Pursuing Administrative and Judicial Remedies.

The fifth *TRAC* factor—"the nature and extent of interests prejudiced by the delay"—also weighs heavily in favor of an order compelling agency action. *Community*, 878 F.3d at 786. Here, FDA's failure to promptly decide the Petition leaves Petitioners' members and the public at risk of exposure to carcinogenic flavors and thus increases the likelihood that individuals may develop cancer.

FDA's failure to decide the Petition also leaves Petitioners "stuck in administrative limbo." *See Mojahedin*, 680 F.3d at 837. In other words, Petitioners "enjoy[] neither a favorable ruling on [the Petition] nor the opportunity to challenge an unfavorable one." *Id*. (observing that an agency's delay in resolving an organization's petition effectively insulated the agency's outstanding

[20] Given its focus on protecting public health, this is not a case where "putting [the petitioners] at the head of the queue simply moves all others back one space and produces no net gain." *See In re Barr Labs., Inc.*, 930 F.2d 72, 75 (D.C. Cir. 1991).

decision from judicial review). In the meantime, individuals across the country will continue to suffer increased risk of cancer from consumption of foods containing carcinogens. The nature and extent of interests prejudiced by FDA's delay thus weigh in favor of mandamus relief.[21]

III. An Order from this Court Compelling FDA to Decide the Petition within 30 Days is Reasonable and Appropriate.

As this Court has explained, where an agency has unlawfully withheld or unreasonably delayed mandatory action, "courts have power and discretion to enforce compliance within some form of timeline." *Community*, 878 F.3d at 788. This Court has repeatedly remedied unreasonable delays by directing agencies to take action within periods measured by days—not years. *See, e.g.*, *id.* (ordering agency to issue an unreasonably delayed proposed rule within 90 days and a final rule one year later); *Pesticide Action Network*, 798 F.3d at 815 (directing agency to take unreasonably delayed action by 82 days from the date the Court's order became final); *see also Auchter*, 702 F.2d at 1158–59 (ordering agency to issue a notice of proposed rulemaking within 30 days and explaining that "we expect

[21] Petitioners do not allege "any impropriety lurking behind" FDA's unlawful failure to decide the Petition, and no such allegation is required. *Community*, 878 F.3d at 786 (quoting *TRAC*, 750 F.2d at 80); *see also id.* at 787 ("Even assuming that EPA has numerous competing priorities under the fourth [*TRAC*] factor and has acted in good faith under the sixth factor, the clear balance of the *TRAC* factors favors issuance of the writ.").

promulgation of a final rule within a year's time"). Where agencies have not merely delayed but, instead, have unlawfully withheld action in violation of federal law, courts may impose even shorter deadlines. *See, e.g.*, *Forest Guardians v. Babbitt*, 164 F.3d 1261, 1274 (10th Cir. 1998), *opinion amended on denial of reh'g*, 174 F.3d 1178 (10th Cir. 1999) (instructing district court to order agency to take action unlawfully withheld "as soon as possible, without regard to the [agency's] other priorities under the [relevant statute]," and noting that courts have ordered agencies to complete such action within as little as 5 and 14 days).

In this, case, an order compelling FDA to decide the Petition within 30 days is reasonable and appropriate. FDA has now been considering the "gold-standard" research and other reliable information Petitioners submitted—some of which has existed in the scientific literature for decades—for 26 months. Thus, FDA has already had more than *eight times* the 90-day period that Congress presumed would be generally sufficient for determining the safety of food additives and more than *four times* the 180-day maximum period allowed under the law. More than enough time has passed without a decision from FDA. Additional delay will only increase the risk of continued exposure to unsafe, cancer-causing flavors, jeopardizing the health of Petitioners' members and the public at large, which is precisely what Congress sought to avoid in enacting the Delaney Clause.

CONCLUSION

For the foregoing reasons, this Court should grant this Petition and issue a writ of mandamus ordering FDA to decide the Petition within 30 days of the order.

Respectfully submitted this 2nd day of May, 2018.

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STATEMENT OF RELATED CASES

Counsel for Petitioners are aware of no related cases pending before this or any other court.

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CERTIFICATE OF COMPLIANCE

This petition for writ of mandamus complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 10,747 words, excluding the parts

exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This petition for writ of mandamus complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word Times New Roman 14-point font.

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LIST OF EXHIBITS

Exhibit 1: Letter from Laura MacCleery, Ctr. For Sci. in the Pub. Interest, et al. to Dennis Keefe, FDA (July 28, 2015)

Exhibit 2: Letter from Erik D. Olson, Nat. Res. Def. Council, et al. to Judith K. Rabaglia, FDA (Oct. 24, 2015)

Exhibit 3: Letter from Erik D. Olson, Nat. Res. Def. Council, et al. to Judith K. Rabaglia, FDA (Feb. 6, 2016)

Exhibit 4: Letter from Tom Neltner, Envtl. Def. Fund to Judith Rabaglia, FDA (Apr. 3, 2018)

Exhibit 5: Letter from Judith Rabaglia, FDA to Tom Neltner, Envtl. Def. Fund (Dec. 17, 2015)

Exhibit 6: Letter from Tom Neltner, Envtl. Def. Fund, to Judy Kidwell, FDA (Feb. 10, 2016)

Exhibit 7: Letter from Judith Rabaglia, FDA, to Tom Neltner, Envtl. Def. Fund (Feb. 12, 2016)

Exhibit 8: E-mail from Judy Kidwell, FDA, to Tom Neltner, Envtl. Def. Fund (July 7, 2016)

LIST OF DECLARATIONS AND ATTACHED EXHIBITS

1. **Declaration of Nancy Buermeyer, Breast Cancer Prevention Partners**

   Exhibit 1: Janet M. Gray et al., *State of the Evidence 2017: An Update on the Connection between Breast Cancer and the Environment*, 16 Envtl, Health 94 (2017).

2. **Declaration of Hendy Dayton, Breast Cancer Prevention Partners**

3. **Declaration of Caroline Cox, Center for Environmental Health**

4. **Declaration of Tina Eshaghpour, Center for Environmental Health**

5. **Declaration of Andrew Kimbrell, Center for Food Safety**

6. **Declaration of Maria Juur, Center for Food Safety**

7. **Declaration of Lisa Y. Lefferts, Center for Science in the Public Interest**

8. **Declaration of Jean Bissell, Center for Science in the Public Interest**

9. **Declaration of Tom Neltner, Environmental Defense Fund**

   Exhibit A: Excerpt from NTP, NTP TR 533, Toxicology and Carcinogenesis Studies of Benzophenone (CAS No. 119-61-9) in F344/N Rats and B6C3F_1 Mice (Feed Studies) (2006)

   Exhibit B: Excerpt from NTP, Technical Report Series No. 259, Carcinogenesis Studies of Ethyl Acrylate (CAS No. 140-88-5) in F344/N Rats and B6C3F_1 Mice (Gavage Studies) (1986)

   Exhibit C: Excerpt from NTP, NTP TR 491 Toxicology and Carcinogenesis Studies of Methyleugenol (CAS No. 93-15-2) in F344/N Rats and B6C3F_1 Mice (Gavage Studies) (2000)

   Exhibit D: Excerpt from NTP, NTP TR 557 Toxicology and Carcinogenesis Studies of ß-Myrcene (CAS No. 123-35-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies) (2010)

Exhibit E: Excerpt from NTP, NTP TR 563, Toxicology and Carcinogenesis Studies of Pulegone (CAS No. 89-82-7) in F344/N Rats and B6C3F1 Mice (Gavage Studies) (2011)

Exhibit F: Excerpt from NTP, NTP TR 470, Toxicology and Carcinogenesis Studies of Pyridine (CAS No. 110-86-1) in F344/N Rats, Wistar Rats, and B6C3F_1 Mice (Drinking Water Studies) (2000)

Exhibit G: NTP, *Methyleugenol: CAS No. 93-15-2, in* Report on Carcinogens (14th ed. 2016)

Exhibit H: NTP, *Styrene: CAS No. 100-42-5, in* Report on Carcinogens (14th ed. 2016)

Exhibit I: Ctr. for Food Safety & Applied Nutrition, FDA, *Carcinogenicity Studies with Rodents, in* Redbook 2000: Guidance for Industry and Other Stakeholders, Toxicological Principles for the Safety Assessment of Food (2006)

Exhibit J: Excerpts from NTP, Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals (2011)

Exhibit K: FEMA, Poundage and Tech. Effects Survey 2010 (2013)

Exhibit L: Sigma-Aldrich, *Flavors of Summer 2016: Our New BBQ and Picnic Inspired Ingredients*, https://www.sigmaaldrich.com/technical-documents/articles/chemistry/flavors-of-summer.html (last visited Apr. 28, 2018)

Exhibit M: Sigma-Aldrich, *Potential Application for Ethyl Acrylate, FG*, https://www.sigmaaldrich.com/technical-documents/articles/chemistry/application-for-ethyl-acrylate.html (last visited Apr. 28, 2018)

Exhibit N: Sigma-Aldrich, Application Guide: High Impact Molecules (3d ed. 2015)

Exhibit O: Arnold Schecter et al., *Human Consumption of Methyleugenol and Its Elimination from Serum*, 112 Envtl. Health Persps. 678 (2004)

10. **Declaration of Maryann Mahood, Environmental Defense Fund**

11. **Declaration of Melanie Benesh, Environmental Working Group**

12. **Declaration of Gina Trujillo, Natural Resources Defense Council**

13. **Declaration of Lori Baines, Natural Resources Defense Council**

14. **Declaration of Rolf Bandle, Natural Resources Defense Council**

15. **Declaration of Anne H. Barker, Natural Resources Defense Council**

16. **Declaration of Adrienne Hollis, WE ACT for Environmental Justice**

17. **Declaration of Castedy Castro, WE ACT for Environmental Justice**

CERTIFICATE OF SERVICE

I hereby certify that I have this day electronically filed the foregoing document and all attachments with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I further certify that I have served the foregoing Petition for a Writ of Mandamus and all related certificates, declarations, and Exhibits, by dispatching them to a third-party commercial carrier for delivery within 3 calendar days to the following parties:

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