No. _____

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

IN RE BREAST CANCER FUND, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, ENVIRONMENTAL WORKING GROUP, and NATURAL RESOURCES DEFENSE COUNCIL, *Petitioners*,

v.

U.S. FOOD AND DRUG ADMINISTRATION and ROBERT M. CALIFF, COMMISSIONER OF THE U.S. FOOD AND DRUG ADMINISTRATION, *Respondents*.

PETITION FOR A WRIT OF MANDAMUS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Working Group, and Natural Resources Defense Council, Inc., submit that they have no parent corporations. No publicly held corporation holds stock in any of the petitioners.

March 31, 2016

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I. INTRODUCTION

Petitioners Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Working Group, and Natural Resources Defense Council seek a Writ of Mandamus from this Court compelling respondents U.S. Food and Drug Administration and Commissioner Robert M. Califf (collectively, FDA or the agency) to decide petitioners' administrative petition to revoke FDA's approval of perchlorate as a food additive (Petition).[1] *See* Hsieh Decl. ¶¶ 2-4 (ADD 3-4); *id*. Ex. A (ADD 8-84); *id*. Ex. B (ADD 85-106). Perchlorate is an endocrine-disrupting chemical that interferes with the thyroid gland. By inhibiting the thyroid's uptake of iodine, perchlorate impairs hormone production crucial to fetal and infant brain development. Data collected by the Centers for Disease Control and Prevention (CDC) have shown that perchlorate is found in the bodies of virtually all Americans. *See id* Ex. C, at 400 (ADD 108).

[1] A "food additive" includes "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 (including any substance intended for use in . . . packaging . . . or holding food . . .)." 21 U.S.C. § 321(s).

Despite the serious health risks posed by perchlorate, FDA has authorized use of perchlorate in sealing gaskets for food containers since 1962.[2] *See* Closures with Sealing Gaskets for Food Containers, 27 Fed. Reg. 7092 (July 26, 1962) (codified at 21 C.F.R. § 177.1210). The agency approved another food-contact use of perchlorate in 2005, authorizing the chemical's use as an antistatic agent in plastic packaging for dry food products. *See* Hsieh Decl. Ex. D, at 1 (ADD 117); *id*. Ex. E, at 1 (ADD 120). Perchlorate is widespread in the American food supply, appearing in a majority of foods sampled by FDA in 2005 and 2006. *See id*. Ex. A, at 17-18 (ADD 25-26); *id*. Ex. F, at 571, 573, 575 (ADD 123, 125, 127). There are no labeling requirements that mandate disclosure of perchlorate in food packaging, and therefore consumers have no way of knowing when they are being exposed to perchlorate through packaged foods.

Petitioners and other concerned groups filed the Petition in 2014, requesting that FDA rescind its approval of perchlorate as a food additive. The Federal Food, Drug, and Cosmetic Act (Food Act) prohibits the sale of food containing unsafe additives, and the Petition set forth significant data and information demonstrating why the uses of perchlorate authorized by FDA are unsafe. The Food Act requires FDA to issue an order granting or denying a food additive petition within 180 days,

[2] A gasket is a "flat, shaped sheet or ring of rubber, cork, metal composite, or other relatively soft material inserted between adjoining . . . surfaces in order to make the joint airtight or watertight." *Oxford English Dictionary* (online ed. 2016).

and the agency's deadline for deciding the Petition was June 29, 2015. That deadline has come and gone without a final response. FDA's failure to timely decide the Petition contravenes the Food Act's central purpose to protect the public from unsafe food and other products. Petitioners thus ask this Court to find that FDA has unlawfully withheld action on the Petition, and to compel FDA to issue a final order deciding the Petition by a date certain.

II. JURISDICTION

Petitioners bring this case pursuant to Federal Rule of Appellate Procedure 21, which allows parties to petition the Court of Appeals for a writ of mandamus. The Food Act vests exclusive jurisdiction in the Courts of Appeals to review final orders by FDA approving or denying food additive petitions. 21 U.S.C. § 348(g). Although FDA has yet to issue a final order deciding petitioners' food additive petition, the All Writs Act authorizes this Court "to issue mandamus relief necessary to protect [its] 'prospective jurisdiction.'" *In re Cal. Power Exch. Corp.*, 245 F.3d 1110, 1119 (9th Cir. 2001) (quoting *Pub. Util. Comm'r of Or. v. Bonneville Power Admin.*, 767 F.2d 622, 630 (9th Cir. 1985)). The Court therefore has jurisdiction to compel FDA to decide the Petition.

Petitioners have standing to bring this action. To establish standing, petitioners must show that the interests they seek to protect are germane to their organizational purposes, that this litigation will not require their members'

individual participation, and that their members would have standing to sue in their own right. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977); *see also Mont. Shooting Sports Ass'n v. Holder*, 727 F.3d 975, 981 (9th Cir. 2013) ("[T]he presence in a suit of even one party with standing suffices to make a claim justiciable . . . ." (quoting *Brown v. City of L.A.*, 521 F.3d 1238, 1240 n.1 (9th Cir. 2008)).

Petitioners satisfy this test. First, protection of human health from unsafe chemical exposures is germane to petitioners' organizational missions. *See* Decl. of Michael F. Jacobson ¶¶ 6-7 (ADD 196-97); Decl. of Andrew Kimbrell ¶¶ 3-8 (ADD 198-201); Decl. of Gina Trujillo ¶¶ 6-7 (ADD 226). 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 Hunt*, 432 U.S. at 344. Third, petitioners' members would have standing to sue on their own because they suffer "injury in fact" that is traceable to FDA's inaction and likely to be redressed by a favorable decision. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

FDA's failure to decide the Petition inflicts a cognizable procedural injury upon petitioners' members. To show such a cognizable injury, petitioners must demonstrate that: (1) FDA violated a certain procedural rule; (2) that rule protects

the concrete interests of petitioners' members; and (3) it is reasonably probable that FDA's challenged inaction will threaten those interests. *See Ctr. for Food Safety v. Vilsack*, 636 F.3d 1166, 1171 (9th Cir. 2011) (citing *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969-70 (9th Cir. 2003)).

This test is satisfied here. First, FDA violated the Food Act's explicit procedural requirement that the agency decide a food additive petition within 180 days. *See* 21 U.S.C. § 348(c)(2); *id*. § 348(i); 21 C.F.R. § 171.100(a). Second, this requirement protects the health interests of petitioners' members by ensuring that FDA promptly considers food additive petitions and, when warranted, takes action to limit the use of a food additive when there is not "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i). Third, it is reasonably probable that FDA's violation of the statutory deadline threatens petitioners' members' health. Perchlorate may migrate from plastic packaging into dry food. *See* Hsieh Decl. Ex. A, at 16-17 (ADD 24-25). Once ingested, the chemical disrupts thyroid function, including hormone production. *See id*. at 2 (ADD 10).

Petitioners' members and their families consume dry foods that may have been contaminated with perchlorate; those foods may have been contaminated either directly through contact with perchlorate-containing packaging, or indirectly through inclusion of ingredients that were held in perchlorate-containing

packaging. *See id*. at 10-11 (ADD 18-19); *id*. Ex. D, at 1 (ADD 117); *id*. Ex. E, at 1 (ADD 120); Decl. of Rachel Azzolini ¶ 6 (ADD 160-61); Decl. of Stephanie Cohen ¶¶ 8-9 (ADD 164-65); Decl. of Christopher Davis ¶¶ 15-16, 21 (ADD 172-75); Decl. of Elizabeth Espy ¶¶ 7-9 (ADD 178-79); Decl. of Teresa Hale ¶¶ 10, 12 (ADD 186); Decl. of Thomas Hawkins ¶¶ 9, 12 (ADD 190-91); Decl. of Kirsten Krane ¶ 8 (ADD 205); Decl. of Richard Luczyski ¶¶ 10, 12-13 (ADD 209-10); Decl. of Matthew Rainbow ¶ 5, 7-8 (ADD 215-16); Decl. of Paige Tomaselli ¶¶ 5, 8, 9, 12 (ADD 221-23). Some of petitioners' members have infants and young children, who are likely to have higher exposure to perchlorate through food packaging because they consume more food per unit body weight than adults do, and thus are particularly vulnerable to the health risks posed by ingestion of perchlorate-contaminated foods. *See* Hsieh Decl. Ex. A, at 18 (ADD 26); Azzolini Decl. ¶¶ 4-7 (ADD 160-61); Cohen Decl. ¶¶ 3, 6-7 (ADD 163-64); Espy Decl. ¶¶ 5-7, 10-16 (ADD 178-80); Krane Decl. ¶¶ 4-8 (ADD 204-05); Rainbow Decl. ¶ 4-5, 8-9 (ADD 215-16); *see also* Luczyski Decl. ¶ 13 (ADD 210). Those members include parents who are concerned about exposing their infants to perchlorate through breastmilk or powdered infant formula. *See* Azzolini Decl. ¶ 6 (ADD 160-61); Tomaselli Decl. ¶¶ 4, 6, 10-12 (ADD 220-22); *see also* Hsieh Decl. Ex. C, at 404 (ADD 112) (describing study that reported measurable levels of perchlorate in all samples of breast milk collected). Another subset of petitioners'

members and their families are also especially susceptible to the health risks posed by perchlorate, as they already suffer from hypothyroidism, a condition in which the thyroid produces insufficient hormones. *See* Davis Decl. ¶¶ 7-8 (ADD 169-70); Hale Decl. ¶¶ 4-7, 9, 11 (ADD 184-86); Hawkins Decl. ¶¶ 6-12, 14 (ADD 190-92); Krane Decl. ¶¶ 4-5, 9 (ADD 204-05); Luczyski Decl. ¶¶ 4-6, 11-12 (ADD 208-10); *see also* Hsieh Decl. Ex. G, at 1 (ADD 134) (describing symptoms associated with hypothyroidism, ranging from fatigue to fertility problems).

Furthermore, it is impossible for petitioners' members to avoid consuming food that may have been contaminated with perchlorate for two reasons. First, FDA allows an extremely broad range of foods, including both final consumer products and their constituent ingredients, to be packaged in materials containing perchlorate; those foods include such common staples as flour, sugar, grains, and pasta. *See infra* Section IV.B. Second, food packaging is not labeled to disclose the presence of perchlorate, so petitioners' members lack the information they need to avoid eating perchlorate-contaminated foods. Even if petitioners' members were able to avoid eating foods packaged in plastic at the point of purchase—which they are not—they would have no way of knowing whether those foods, or their component ingredients, had been held in perchlorate-containing packaging at some point in the production and distribution chain. *See* Hsieh Decl. Ex. A, at 10-11 (ADD 18-19); Azzolini Decl. ¶ 6 (ADD 160-61); Cohen Decl. ¶¶ 8-9 (ADD 164-

65); Davis Decl. ¶¶ 15-16 (ADD 172-73); Espy Decl. ¶¶ 9, 15-16 (ADD 179-80); Hale Decl. ¶ 12 (ADD 186); Hawkins Decl. ¶¶ 12-14 (ADD 191-92); Krane Decl. ¶ 8 (ADD 205); Rainbow Decl. ¶ 10 (ADD 216); Tomaselli Decl. ¶ 9 (ADD 221-22); *cf. Nat. Res. Def. Council v. U.S. E.P.A.*, 735 F.3d 873, 879 (9th Cir. 2013) (holding that the Natural Resources Defense Council demonstrated a cognizable injury to its members from the U.S. Environmental Protection Agency (EPA)'s approval of a pesticide, where the "probability of exposure to the risk of harm is quite high" and "the probability that NRDC's members will be able to avoid exposing their children to the risk of harm is quite low").

The Petition presented FDA with information and data explaining how the agency, in approving the challenged uses of perchlorate, underestimated not only consumers' exposure to perchlorate, but also the health risks posed by that exposure. *See generally* Hsieh Decl. Ex. A, at 1-12 (ADD 9-20). The Petition also set forth "significant new information" warranting reconsideration of whether the authorized uses of perchlorate are safe. 21 C.F.R. § 170.39(g); *see generally* Hsieh Decl. Ex. A, at 12-20 (ADD 20-28). FDA's failure to decide the Petition thus threatens petitioners' interests in consuming food free of potentially harmful levels of perchlorate.

"Once plaintiffs seeking to enforce a procedural requirement establish a concrete injury, 'the causation and redressability requirements are relaxed.'"

WildEarth Guardians v. U.S. Dep't of Agric., 795 F.3d 1148, 1154 (9th Cir. 2015) (quoting *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 485 (9th Cir. 2011)). "'Plaintiffs alleging procedural injury must show only that they have a procedural right that, if exercised, *could* protect their concrete interests.'" *Id.* (quoting *Salmon Spawning & Recovery Alliance v. Gutierrez*, 545 F.3d 1220, 1226 (9th Cir. 2008)). FDA's failure to timely decide the Petition subjects petitioners' members to continued risk of exposure to harmful levels of perchlorate through consumption of contaminated foods. If FDA were to decide the Petition, it could agree to ban or limit the uses of perchlorate that injure petitioners' members, thereby protecting their health interests. *See* Cohen Decl. ¶¶ 13-14 (ADD 165-66); Davis Decl. ¶¶ 20-21 (ADD 174-75); Espy Decl. ¶ 20 (ADD 181); Hawkins Decl. ¶¶ 16-17 (ADD 192-93); Luczyski Decl. ¶ 16 (ADD 211); Rainbow Decl. ¶¶ 12, 14 (ADD 216-17); Tomaselli Decl. ¶¶ 14-15 (ADD 223). Alternatively, if FDA were to deny the petition, petitioners would have the right to challenge that decision on the merits; if petitioners were to prevail on such a challenge, this would also protect their members' health interests. *See* Cohen Decl. ¶ 15 (ADD 166); Davis Decl. ¶ 22 (ADD 175); Espy Decl. ¶¶ 21-22 (ADD 181-82); Luczyski Decl ¶¶ 17-18 (ADD 211); Rainbow Decl. ¶ 15 (ADD 217); Tomaselli Decl. ¶ 16 (ADD 223-24).

III. LEGAL FRAMEWORK

The Food Act prohibits the introduction of any "adulterated" food into interstate commerce. 21 U.S.C. § 331(a). A food is "adulterated" if it contains an "unsafe" food additive. *Id*. § 342(a)(2)(C)(i). A food additive may be a "food contact substance," which the Food Act defines as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." *Id.* § 348(h)(6). In addition, FDA has defined "[s]afe or safety" to "mean[] that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i).

The Food Act requires that a food additive be deemed "unsafe" unless, as relevant here, FDA has approved it by issuing a regulation "prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a). In addition, "[a] substance used in a food-contact article (e.g., food-packaging . . .) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation," among other criteria. 21 C.F.R. § 170.39(a); *see also id.* § 170.39(a)(2)(i) (requiring that use of such an exempted substance "has been shown to result in or may be expected to result in dietary concentrations

at or below 0.5 parts per billion, corresponding to dietary exposure levels at or below 1.5 micrograms/person/day"[3]). In determining whether a proposed use of a food additive is safe, FDA must consider, among other relevant factors, "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet." 21 U.S.C. § 348(c)(5)(B). In addition, if FDA "receives significant new information that raises questions about the dietary concentration or the safety of a substance that the agency has exempted from regulation, the Food and Drug Administration may reevaluate the substance." 21 C.F.R. § 170.39(g).

Any interested person may submit a food additive petition to FDA asking it to issue, amend, or repeal a food additive regulation. 21 U.S.C. § 348(b)(1), (i); 21 C.F.R. § 171.130. If FDA finds the petition to be deficient or incomplete, the petitioner may supplement and resubmit it. 21 C.F.R. § 171.1(d), (i)(1)(ii). Once the petition has been filed, the agency has ninety days to decide whether or not it will issue, amend, or repeal the relevant regulation. *See* 21 U.S.C. § 348(c)(2), (i); 21 C.F.R. § 171.100(a). FDA can take an additional ninety days if "necessary to enable [the agency] to study and investigate the petition." 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100(c). However, FDA "shall" approve or deny a food additive

[3] A microgram is one-millionth of a gram.

petition within 180 days of the petition's filing date. 21 U.S.C. § 348(c)(2); *see id*. § 348(i); 21 C.F.R. § 171.100.

The Food Act sets forth specific actions that FDA must take to approve or deny a food additive petition. In response to a petition to promulgate a new regulation, FDA shall either "by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing . . . the conditions under which such additive may be safely used," 21 U.S.C. § 348(c)(1)(A), or "by order deny the petition, and . . . notify the petitioner of such order and of the reasons for such action," *id*. § 348(c)(1)(B). In response to a petition to amend or repeal an existing food additive regulation, FDA must follow a procedure that "conform[s] to the procedure provided . . . for the promulgation of such regulations." *Id*. § 348(i). In other words, the agency must by order amend or repeal the targeted food additive regulation or by order deny the petition. *See id*. § 348(c)(1), (i).

IV. FACTUAL BACKGROUND

A. Perchlorate poses serious human health risks

Perchlorate is a chemical that interferes with the thyroid gland. Hsieh Decl. Ex. A, at 2 (ADD 10). By inhibiting the thyroid's uptake of iodine, perchlorate impairs hormone production. *Id*. Thyroid hormones are, among other things, critical to fetal and infant brain development. *Id*. A pregnant woman's ingestion of perchlorate is especially dangerous during the first two trimesters of pregnancy,

when the fetus's thyroid is not fully functioning and the fetus depends entirely on maternal thyroid hormones. *Id.* Even transient exposures to perchlorate may result in permanent cognitive deficits in children. *Id.*

Risk of harm from perchlorate is particularly high for fetuses carried by pregnant women who already have deficient iodine intake. *Id*. As it is, most pregnant women do not consume sufficient iodine. *Id*. The World Health Organization defines adequacy of iodine intake by the concentration of urinary iodine and sets a concentration of less than 150 µg/L (or micrograms per liter) as inadequate for pregnant women. *Id.* Based on this benchmark and data from the National Health and Nutrition Examination Survey (NHANES) administered by CDC from 2007 to 2010, almost 56% of pregnant women have inadequate iodine intake. *Id*. Risk of harm from maternal perchlorate exposure is particularly high for fetuses carried by the 26.3% of pregnant women with urinary iodine concentrations of less than 100 µg/L, and even more acute for fetuses carried by the 15.7% of pregnant women with concentrations less than 50 µg/L. *Id*.

Exposure to perchlorate is pervasive among Americans. *Id.* Urinary perchlorate levels reflect recent exposure, and a 2001-2002 NHANES survey of 2820 U.S. residents, ages six and older, found detectable levels of perchlorate in all urinary samples. *Id*. Ex. C, at 400 (ADD 108). The samples also showed significantly higher levels of urinary perchlorate in children as compared to adults.

Id. In addition, perchlorate contamination is widespread in the American food supply. *Id*. Ex. A, at 2, 17-18 (ADD 10, 25-26). A 2008 FDA study found that 74% of 285 tested food types had at least one sample containing measurable levels of perchlorate; in addition, about 59% of the 1,065 individual food samples had detectable levels of perchlorate. *Id.* at 17-18 (ADD 25-26); *Id.* Ex. F, at 575 (ADD 127). Recent studies show that there may be substantial migration of perchlorate from plastic packaging into dry foods. *See id*. Ex. A, at 16-17 (ADD 24-25).

In addition to being widely present in the food supply, perchlorate also contaminates drinking water. In 2011, EPA concluded that perchlorate must be regulated under the Safe Drinking Water Act, to protect against health harm by limiting human exposure through drinking water. Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762, 7762 (Feb. 11, 2011). EPA found that "perchlorate may have an adverse effect on the health of persons" and "is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern." *Id*. Accordingly, Americans may be exposed to perchlorate not only through the food they eat, but also the water they drink.

B. FDA has approved two uses of perchlorate as a food additive

In 1962, FDA approved use of the salt potassium perchlorate in closure-sealing gaskets for food containers. *See* Closures with Sealing Gaskets for Food

Containers, 27 Fed. Reg. 7092 (July 26, 1962) (codified at 21 C.F.R. § 177.1210). Closure-sealing gaskets are intended to close food containers hermetically to prevent entry of oxygen, which may otherwise cause discoloration of the packaged product. *See, e.g.*, Hsieh Decl. Ex. H, at 1 (ADD 141). In containers with metal closures, the presence of an electric current can cause corrosion, allowing oxygen to enter. *Id.* Because of its antistatic properties, *see id*. Ex. D., at 1 (ADD 117), perchlorate is presumably used in closure-sealing gaskets for food containers to suppress electric currents that might otherwise lead to corrosion.[4]

In 2005, FDA also granted a "threshold of regulation" exemption (TOR No. 2005-006) allowing use of the compound sodium perchlorate monohydrate as an antistatic agent in plastic packaging for dry solid foods with surfaces containing no free fat or oil. *See id.*; *id*. Ex. E, at 1 (ADD 120); 21 C.F.R. § 170.39(a). Under this exemption, sodium perchlorate monohydrate "may be used at a level not to exceed 1.2 percent by weight of the finished polymer." Hsieh Decl. Ex. D, at 1 (ADD 117). In this capacity, perchlorate reduces the electrostatic charge created during the filling, emptying, and transporting of food containers. *Id*. Ex. A, at 11 (ADD 19); *id*. Ex. J, at 1 (ADD 148). It also decreases the electrostatic charge on film

[4] The Society of the Plastics Industry, the trade association for plastics manufacturers, has represented to FDA that "domestic and foreign producers of perchlorates may not currently manufacture perchlorate for use in closure sealing gaskets for food containers." Hsieh Decl. Ex. I, at 1 (ADD 145). To the extent that perchlorate is still used in food container sealing gaskets, the Society of the Plastics Industry's statement to FDA suggests that superior alternatives exist.

surfaces, preventing dust deposit and preserving the original appearance of packaging. *Id*. Ex. A, at 11 (ADD 19). FDA's exemption permits use of perchlorate in packaging for both raw food ingredients and final consumer products. *See id.* at 10-11 (ADD 18-19). The breadth of the exemption, moreover, allows perchlorate to be used in packaging for an extremely wide range of ingredients and commodities, including not only staples like cereals, grains, beans, and pastas, but also basic substances like flour and sugar. *See id*. Ex. D, at 1 (ADD 117); *id*. Ex. E, at 1 (ADD 120).

C. Petitioners petitioned FDA to revoke its approval of perchlorate as a food additive, because there is not reasonable scientific certainty that those uses are safe

In 2014, petitioners and other concerned groups submitted a food additive petition to FDA requesting that the agency rescind its approved uses of perchlorate in food packaging. Specifically, the Petition asked FDA to: (1) revoke the exemption, referred to as TOR No. 2005-006, allowing use of sodium perchlorate monohydrate as an antistatic agent in packaging for dry foods; (2) promulgate a new regulation prohibiting use of perchlorate as an antistatic agent in food contact articles; and (3) amend the regulation permitting use of potassium perchlorate in sealing gaskets for food containers, 21 C.F.R. § 177.1210, to prohibit that use. Hsieh Decl. Ex. A, at 1 (ADD 9).

The Petition highlighted significant reasons why there is not "reasonable certainty in the minds of competent scientists that [perchlorate] is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i). First, it identified serious flaws in the assumptions and analyses underlying FDA's decisions to allow use of perchlorate as a food additive. *See* Hsieh Decl. Ex. A, at 2-12, 19-20 (ADD 10-20, 27-28). For example, FDA failed to consider adequately "the cumulative effect of [perchlorate] in the diet of man or animals." 21 U.S.C. § 348(c)(5)(B). Despite widespread concern about perchlorate contamination in drinking water, the agency did not take into account consumers' exposure to perchlorate through that pathway. Hsieh Decl. Ex. A, at 6 (ADD 14). In other words, in deciding whether exposure to perchlorate from food packaging was safe, FDA ignored the fact that consumers are already exposed to perchlorate through drinking water.

In addition, FDA underestimated the daily intake of perchlorate for infants and young children from food packaging by assuming that infants and young children would ingest no more perchlorate per unit body weight than adults do. *See id.* at 10 (ADD 18). However, infants and adults consume more food per unit of body weight than do adults, and are thus likely to have greater exposure to perchlorate from consumption of contaminated foods. *Id.* FDA neglected to address, moreover, the possibility that a larger proportion of infants' and children's diets may be comprised of perchlorate-contaminated foods, as exemplified by an

infant whose sole source of nutrition is perchlorate-contaminated powdered formula. *Id*. Notably, data confirm that children have significantly higher exposure to perchlorate than do adults. *Id*. at 18 (ADD 26); *see id*. Ex. C, at 400 (ADD 108). Furthermore, FDA failed to consider that perchlorate could enter consumers' diets not only through the packaging of final dry food products sold to consumers, but also through the packaging of the dry food ingredients used in the processing and manufacture of those products. *Id*. Ex. A, at 10-11 (ADD 18-19). FDA also overlooked a mathematical error that underestimated dietary intake of perchlorate by eighty-three times. *Id*. at 7-8 (ADD 15-16).

Next, the Petition presented "significant new information" that warranted reconsideration of whether the FDA-approved uses of perchlorate are safe. 21 C.F.R. § 170.39(g); *see* Hsieh Decl. Ex. A, at 12-19 (ADD 20-27). First, in approving the use of perchlorate as an antistatic agent in food packaging "at a level not to exceed 1.2 percent by weight of the finished polymer," *id*. Ex. D, at 1 (ADD 117), FDA relied on a "reference dose" of 0.7 µg/kg body weight/day (or micrograms per kilogram of body weight per day), meaning that the agency assumed that consumers could safely ingest perchlorate at that rate. *Id*. Ex. A, at 13 (ADD 21). For example, under this reference dose, FDA assumes that a 60 kilogram (or 132 pound) woman could safely consume up to 42 micrograms of perchlorate per day. In 2013, however, EPA's Scientific Advisory Board

concluded that this reference dose is too high and does not provide sufficient protection to susceptible populations, including pregnant women. *Id*. EPA's determination means that sensitive populations could be harmed by consuming perchlorate at a dose of 0.7 µg/kg body weight/day. Because FDA's approval of perchlorate for use in plastic food packaging was based on this inappropriately high reference dose, there is not reasonable certainty that humans can safely consume food held in plastic packaging that contains up to 1.2% perchlorate by weight.

Second, since 2005, research has shown that other chemicals—specifically nitrates and thiocyanates—are pharmacologically-related to perchlorate and have a common mechanism of toxicity: all three interfere with the thyroid's uptake of iodine and its ability to make hormones essential to fetal and infant brain development. *Id*. at 15-16 (ADD 23-24). The widespread presence of these other chemicals, particularly nitrates, in food and food packaging, calls for a new analysis of the cumulative effects of perchlorate's food-additive uses. *Id.* at 16 (ADD 24); *see* 21 U.S.C. § 348(c)(5) (requiring FDA to consider, in determining "whether a proposed use of a food additive is safe," "the cumulative effect of [perchlorate] in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet").

Third, FDA's 2008 study finding widespread perchlorate contamination in the American food supply likewise constitutes "significant new information," 21 C.F.R. § 170.39(g), about "the cumulative effect of [perchlorate] in the diet of man," 21 U.S.C. § 348(c)(5). Finally, in approving perchlorate for use as an antistatic agent in food packaging, FDA assumed that only 50 parts per billion (ppb) of the chemical migrates into food—a level described as "virtually nil." Hsieh Decl. Ex. A, at 7, 16-17 (ADD 15, 24-25). However, new research from the European Union shows substantial migration of chemicals from plastic packaging into dry food, and FDA has acknowledged that the 50 ppb migration assumption may be flawed. *Id*. at 16-17 (ADD 24-25). These new data, set forth in the Petition, further negate any reasonable scientific certainty that the approved uses of perchlorate are safe. *See* 21 C.F.R. § 170.3(i).

After written exchanges through which FDA identified alleged deficiencies in the Petition and petitioners responded to the agency's comments, FDA accepted the final version of the Petition for filing on December 31, 2014. *See* Hsieh Decl. Ex. K (ADD 156); Notice of Petition, 80 Fed. Reg. 13508, 13509 (Mar. 16, 2015). On March 31, 2015, FDA requested an additional ninety days to respond to the Petition. *See* Hsieh Decl. Ex. L (ADD 158). FDA's 180-day deadline for approving or denying the Petition expired on June 29, 2015. The agency has yet to decide the Petition.

V. ARGUMENT

FDA has unlawfully withheld action on the Petition in violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706(1), and Food Act, 21 U.S.C. § 348, and the Court should issue a writ of mandamus compelling FDA to decide the Petition by a date certain.

A. FDA has unlawfully withheld agency action by failing to decide the Petition by the Food Act's deadline

The APA authorizes a reviewing court to "compel agency action unlawfully withheld," 5 U.S.C. § 706(1), and an agency's failure to make a mandatory decision by a statutory deadline constitutes action unlawfully withheld, *see Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63-65 (2004). Under the Food Act, FDA "shall" issue an order deciding a food additive petition "not more than one hundred and eighty days after the date of filing of the petition." 21 U.S.C. § 348(c)(2), (i). This statutory deadline is mandatory. *See In re Barr Labs., Inc.*, 930 F.2d 72, 74 (D.C. Cir. 1991) (holding as mandatory a similarly-worded provision of the Food Act stating that FDA "shall" approve or disapprove a generic drug application "within one hundred and eighty days of the initial receipt of an application"); *see also Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661 (2007) (collecting cases that interpret the word "shall" to create mandatory obligations). Because FDA accepted the Petition for filing on December 31, 2014, the Food Act required the agency to decide the Petition by June 29, 2015.

See 21 U.S.C. § 348(c)(2), (i). By failing to issue an order granting or denying the Petition by that deadline, FDA has unlawfully withheld agency action. 5 U.S.C. § 706(1).

B. FDA's failure to publish an order deciding the Petition warrants mandamus relief

1. Petitioners satisfy the Ninth Circuit's general mandamus test, and a writ is appropriate under the circumstances

To determine whether mandamus should issue, the Ninth Circuit generally applies a three-part test: whether "(1) the plaintiff's claim is clear and certain; (2) the duty is ministerial and so plainly prescribed as to be free from doubt; and (3) no other adequate remedy is available." *In re Cal. Power Exch. Corp*., 245 F.3d at 1120 (quoting *Or. Natural Res. Council v. Harrell*, 52 F.3d 1499, 1508 (9th Cir. 1995)); *cf. In re Paralyzed Veterans of Am*., 392 F. App'x 858, 860 (Fed. Cir. 2010) (applying similar test to determine whether court should grant mandamus relief to compel agency action, where agency failed to meet statutory deadline). Mandamus is "an extraordinary remedy justified only in exceptional circumstances," and "[t]he party seeking mandamus relief must establish that its right to issuance of the writ is clear and indisputable." *In re Cal. Power Exch. Corp*., 245 F.3d at 1120 (internal quotation marks omitted). Thus, even when the other prerequisites have been met, "the issuing court, in the exercise of its

discretion, must be satisfied that the writ is appropriate under the circumstances." *In re United States*, 791 F.3d 945, 955 (9th Cir. 2015).

An order compelling FDA to decide the Petition by a prompt deadline is warranted under this test. First, petitioners' claim is "clear and certain," *In re Cal. Power Exch. Corp.*, 245 F.3d at 1120, because the Food Act unambiguously required FDA to approve or deny the Petition within 180 days of the filing of the petition. *See* 21 U.S.C. § 348(c)(2), (i); *see also* 21 C.F.R. §§ 171.100(a), 171.130(a). Second, "[a]n agency 'ministerial act' for purposes of mandamus relief has been defined as a clear, non-discretionary agency obligation to take a specific affirmative action, which obligation is positively commanded and so plainly prescribed as to be free from doubt." *Indep. Mining Co. v. Babbitt*, 105 F.3d 502, 508 (9th Cir. 1997) (internal quotation marks omitted). FDA's duty to decide the Petition is "ministerial," because the Food Act clearly commanded FDA to take one of two discrete actions within 180 days of accepting the Petition for filing: either (1) "by order" establish, amend, or repeal the food additive regulations at issue, or (2) "by order deny the petition." 21 U.S.C. § 348(c)(1); *see id.* § 348(i). Third, no other adequate remedy is available. Neither the Food Act nor its implementing regulations provide any other means by which Petitioners can compel FDA to decide the petition. *Cf. Cole v. U.S. Dist. Court for the Dist. of Idaho*, 366 F.3d 813, 817-18 (9th Cir. 2004) (holding that another adequate remedy

was available where petitioners could have sought reconsideration of magistrate judge's order from district court).

In addition, a writ of mandamus "is appropriate under the circumstances," *In re United States*, 791 F.3d at 955, because a prompt decision on the Petition is necessary to effectuate the Food Act's central purpose. The Supreme Court has recognized that the Food Act "was designed primarily to protect consumers" from unsafe products. *United States v. Sullivan*, 332 U.S. 689, 696 (1948). The deadline mandated by the Food Act for responding to food additive petitions reflects Congress's judgment that timely food safety determinations are critical to protecting public health. *Cf. Mohasco Corp. v. Silver*, 447 U.S. 807, 825-26 (1980) ("By choosing what are obviously quite short deadlines, Congress clearly intended to encourage . . . prompt processing . . . . . [I]n a statutory scheme in which Congress carefully prescribed a series of deadlines measured by numbers of days—rather than months or years—we may not simply interject an additional 60-day period into the procedural scheme."). Time is of the essence, moreover, given the risk of serious and irreparable harm to children's health from exposure to perchlorate in food.

The Supreme Court has underscored that "[t]he high purpose of the [Food Act] [is] to protect consumers who under present conditions are largely unable to protect themselves" in the field of food and drug safety. *Kordel v. United States*,

335 U.S. 345, 349 (1948); *accord United States v. Dotterweich*, 320 U.S. 277, 280 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."). This admonition is particularly applicable here. Because there are no labeling requirements for disclosure of perchlorate used in food packaging, consumers have no way of knowing when they are being exposed to perchlorate through packaged foods. *See, e.g.*, Cohen Decl. ¶ 8 (ADD 164-65); Davis Decl. ¶ 16 (ADD 173); Espy Decl. ¶¶ 15-16 (ADD 180); Hale Decl. ¶ 12 (ADD 186); Hawkins Decl. ¶ 13 (ADD 191); Rainbow Decl. ¶ 10 (ADD 216). And even if the packaging for final consumer food products were labeled to disclose the presence of perchlorate, consumers would still not know whether any of the component ingredients incorporated into those food products had been held in packaging containing perchlorate.

"[T]he purpose of the [Food Act]—to safeguard the consumer from the time the food is introduced into the channels of interstate commerce to the point that it is delivered to the ultimate consumer—would be substantially thwarted," *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92 (1964), by FDA's continued inaction on the Petition. There are thus "exceptional circumstances" here that

justify the "extraordinary remedy" of mandamus. *In re Cal. Power Exch. Corp.*, 245 F.3d at 1120 (internal quotation marks omitted).

2. Alternatively, petitioners are also entitled to mandamus relief under the *Badgley* test

Petitioners see no reason why the Ninth Circuit's general mandamus test would not apply here. Nonetheless, in *Biodiversity Legal Foundation v. Badgley*, 309 F.3d 1166, 1177 (9th Cir. 2002), this Court applied a slightly different framework for determining whether court intervention was warranted to compel agency action unlawfully withheld. In *Badgley*, the Ninth Circuit held that "the test for determining if equitable relief is appropriate is whether an injunction is necessary to effectuate the congressional purpose behind the statute." *Id*. at 1177; *cf. Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 971-72 (N.D. Cal. 2013) (granting injunctive relief to compel FDA to finalize various food safety regulations based on the Food Safety Modernization Act's "evident purpose . . . to ensure the safety of the food supply" when, at the time of the complaint, FDA's regulations were approximately two to eleven months overdue). The *Badgley* standard may not be apposite here, as that case involved a request for injunctive relief, whereas Petitioners seek mandamus relief. *But cf. 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."); *see also United States v. Carter*, 270 F.2d 521, 524 (9th Cir. 1959) ("'Although

classed as a legal remedy, . . . issuance [of the writ of mandamus] is largely controlled by equitable principles."' (quoting *Duncan Townsite Co. v. Lane*, 245 U.S. 308, 312 (1917)).

Should this Court decide that *Badgley* governs here, Petitioners also satisfy the *Badgley* test for court intervention. Mandamus is warranted under *Badgley* because a prompt decision of the Petition "is necessary to effectuate the congressional purpose behind the statute." 309 F.3d at 1177. As discussed above, the Food Act's central purpose is to protect consumers from unsafe products, and FDA's 180-day statutory deadline for responding to food additive petition reflects Congress's judgment that timely food safety determinations are critical to protecting public health. *See supra* Section V.B.1. The serious and irreparable health risks that perchlorate poses to fetuses, infants, and children further underscore the need for a swift FDA decision on the Petition. Additional delay would hinder the Food Act's primary objective of protecting consumers, particularly given consumers' inability to protect themselves from the health risks posed by perchlorate exposure through food packaging. *See id.*

VI. REQUEST FOR RELIEF

Petitioners request that the Court grant this Petition for a Writ of Mandamus and order FDA to decide the Petition within ninety days of the Court's order.

VII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Court grant this Petition for a Writ of Mandamus.

March 31, 2016

Respectfully submitted,

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STATEMENT OF RELATED CASES

Petitioners are unaware of any related cases within the definition of Circuit Rule 28-2.6.

March 31, 2016

/s/ Margaret T. Hsieh
Margaret T. Hsieh

/s/ Cristina R. Stella
Christina R. Stella

CERTIFICATE OF SERVICE

I hereby certify that on March 31, 2016, I served a copy of the foregoing Petition for a Writ of Mandamus, and Declarations of Margaret T. Hsieh (and Exhibits A-L), Rachel Azzolini, Stephanie Cohen, Christopher Davis, Elizabeth Espy, Teresa Hale, Thomas Hawkins, Michael F. Jacobson, Andrew Kimbrell, Kirsten Krane, Richard Luczyski, Matthew Rainbow, Paige Tomaselli, and Gina Trujillo by placing true copies thereof in sealed envelopes addressed as shown below for service as designated below:

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Certified Mail, Return Receipt Requested: I placed the envelopes, sealed with first-class postage fully prepaid, and with certified mail labels and return receipts attached, for collection and mailing at a facility regularly maintained by the United States Postal Service.

I declare under penalty of perjury under the laws of the State of New York that the foregoing is true and correct. Executed this March 31, 2016, in New York, New York.

/s/ Gabriel Levine
Gabriel Levine