No. _____

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IN RE
ENVIRONMENTAL DEFENSE FUND, LEARNING DISABILITIES ASSOCIATION OF AMERICA, CENTER FOR FOOD SAFETY, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, BREAST CANCER PREVENTION PARTNERS, DEFEND OUR HEALTH, and ALASKA COMMUNITY ACTION ON TOXICS,

Petitioners.

PETITION FOR WRIT OF MANDAMUS

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GLOSSARY

APA	Administrative Procedure Act
EDF	Environmental Defense Fund
FDA	U.S. Food and Drug Administration
Food Act	Federal Food, Drug, and Cosmetic Act
Food Safety Groups	Collectively, Petitioners Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, and other allied organizations that submitted Food Additive Petition No. 6B4815 in 2016
Petition	Food Additive Petition No. 6B4815 Nat. Res. Def. Council et al., *Food Additive Petition Regarding 30 Ortho-Phthalates Submitted to FDA Pursuant to 21 USC § 348* (Mar. 18, 2016) (Declaration of Tom Neltner, Ex. 1)
Petitioners	Petitioners Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend Our Health, and Alaska Community Action on Toxics
Phthalates	Ortho-phthalate esters

INTRODUCTION

Petitioners Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend Our Health, and Alaska Community Action on Toxics respectfully request a writ of mandamus directing Respondents, the U.S. Food and Drug Administration ("FDA") and its Acting Commissioner, to issue a final decision on Food Additive Petition No. 6B4815 (the "Petition") within sixty days.

In March 2016, six of the Petitioners in this proceeding and other allied organizations (collectively, the "Food Safety Groups"), submitted the Petition asking FDA to revoke its authorizations for uses of more than two dozen ortho-phthalate esters (a class of chemicals referred to here as "phthalates") in food packaging and processing materials. In light of the well-established evidence that FDA-approved phthalates leach out of these materials into food and drinks, and the growing body of scientific studies linking phthalate exposure to serious health harms—including birth defects, infertility, miscarriage, and irreversible harm to the developing brain—the Petition argued that FDA can no longer conclude with reasonable certainty that these substances are safe for their approved uses, as the Federal Food, Drug, and Cosmetic Act (the "Food Act") requires.

The Food Act requires FDA to issue a final decision granting or denying a food additive petition within no more than 180 days. After requesting, and receiving, substantial additional data and analysis from the Food Safety Groups to support the Petition, FDA agreed to take the Petition out of abeyance on March 12, 2018, and complete its decision-making process as the Food Act requires. Yet more than three and a half years later, FDA still has not acted.

As a result, Petitioners' members and supporters and their children have experienced years of phthalate exposure through their diet that poses serious risks to their health, and this exposure continues while FDA withholds a decision on the Petition. Given FDA's violation of its clear statutory duty to take final action on the Petition within 180 days and the significant health harm caused by FDA's years-long delay, a writ of mandamus is both necessary and appropriate to compel FDA to act.

STATEMENT OF RELIEF SOUGHT

Petitioners seek a writ of mandamus directing FDA to issue a final decision granting or denying the Petition within sixty days.

STATEMENT OF JURISDICTION

This Court has jurisdiction to compel FDA to act on the Petition under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702, 706(1), and authority to issue a writ of mandamus under the All Writs Act, 28 U.S.C. § 1651(a).

The Food Act vests exclusive jurisdiction in the Court of Appeals to review final FDA orders on food additive petitions and states that venue is proper in the Circuit where the petitioner resides or in this Circuit. 21 U.S.C. § 348(g)(1). Because the Court of Appeals would have exclusive jurisdiction to review FDA's final order granting or denying the Petition, the Court of Appeals likewise possesses exclusive jurisdiction to review FDA's failure to act on the Petition. *Telecomms. Rsch. & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 78–79 (D.C. Cir. 1984); *see also In re Nat. Res. Def. Council*, 645 F.3d 400, 404–05 (D.C. Cir. 2011). This Court therefore has jurisdiction to issue a writ of mandamus compelling FDA to issue a final order granting or denying the Petition.

ISSUE PRESENTED

Whether FDA's failure to issue an order granting or denying the 2016 Petition more than three and a half years after FDA agreed to take the Petition out of abeyance and make a final decision violates the Food Act and its implementing regulations, 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100, constitutes agency action unlawfully withheld in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1), and warrants mandamus relief from this Court.

STATEMENT OF THE CASE

I. FDA-APPROVED PHTHALATES HAVE CONTAMINATED OUR FOOD SUPPLY, ENDANGERING HUMAN HEALTH

Phthalates are a class of chemicals with similar chemical structures and similar processes through which they are metabolized in the human body. Nat. Res. Def. Council et al., *Food Additive Petition Regarding 30 Ortho-Phthalates Submitted to FDA Pursuant to 21 USC § 348*, at 2–8 (Mar. 18, 2016) (the "Petition") (Declaration of Tom Neltner, Ex. 1); Declaration of Russ B. Hauser, M.D., Sc.D., M.P.H. ¶ 2.[1] For decades, FDA has authorized the use of numerous phthalates in food packaging and processing materials. Most of the time, phthalates are added to these materials to make rigid plastic components more flexible. Hauser Decl. ¶¶ 2, 14. Because phthalates do not chemically bind to the materials to which they are added, they are known to leach into the food and beverages the materials touch. *Id.* ¶ 15. As a result, diet is the primary way that people in the United States—including infants and children—are exposed to most phthalates. Declaration of Ami R. Zota, Sc.D., M.S. ¶¶ 3, 16; Hauser Decl. ¶ 17.

Decades of scientific research link phthalate exposure to serious health harms, and leading experts have identified exposure to phthalates in food as an urgent public health problem. Hauser Decl. ¶¶ 30, 37; Zota Decl. ¶¶ 29, 31–32.

[1] The declarations cited in this petition are provided in the accompanying Addendum.

Phthalates are known endocrine disruptors, meaning they interfere with hormone-regulated processes in the human body. Hauser Decl. ¶ 19. Phthalate exposure is associated with serious reproductive harms to both women and men, including infertility, pregnancy complications, miscarriages, and birth defects involving abnormal development of the male reproductive tract. *Id.* ¶¶ 18–22. Phthalate exposure also is associated with the development and increased severity of uterine fibroids, more severe perimenopausal symptoms, and other health effects in women. *Id.* ¶¶ 22–23; Zota Decl. ¶ 27.

Further, a growing body of evidence links phthalate exposure—particularly among pregnant women, infants, and young children—with irreversible damage to brain development. Phthalates are known to transfer from a pregnant woman's blood into her developing fetus. Hauser Decl. ¶ 26. This exposure *in utero* can damage the developing brain, placing children at higher risk of behavioral disorders, learning disabilities, and reduced IQ. *Id.* ¶¶ 27, 30; Zota Decl. ¶¶ 4, 29. Phthalate exposure in early childhood also is linked with life-altering effects on brain development, including reduced social responsiveness, poorer working memory, and attention and behavior disorders. Hauser Decl. ¶ 30.

Indeed, in 2014, the U.S. Consumer Product Safety Commission's expert panel on phthalates concluded that eight phthalates addressed in the Petition should be banned from use in toys and childcare articles because of their health hazards,

Hauser Decl. ¶ 31, and Congress and the Commission have done so, 15 U.S.C. § 2057c; Final Rule, Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938 (Oct. 27, 2017). In issuing its ban, the Consumer Product Safety Commission recognized that food and drinks are a critically important source of phthalate exposure among infants, young children, and pregnant women. Hauser Decl. ¶ 31. Yet all eight of these phthalates remain FDA-approved for use in food packaging and processing materials from which they are known or expected to leach into food. *Id.*[2]

Phthalate contamination of food and drinks increases when there is prolonged contact between food and materials containing phthalates and in higher-fat foods such as milk and other dairy products, meats, and oils. Zota Decl. ¶¶ 20–21. Higher levels of phthalate exposure are also associated with more frequent consumption of restaurant, takeout, and cafeteria meals, as well as highly processed foods including infant formula. *Id*. ¶¶ 18, 20–21, 25; Hauser Decl. ¶ 17. At the same time, large-scale studies indicate that certain phthalates can be found in most sampled foods—including baked goods, grains, boxed macaroni and cheese, milk and other dairy products, meats, seafood, spices, oils, canned fruits

[2] In March 2021, the U.S. Court of Appeals for the Fifth Circuit remanded the Consumer Product Safety Commission's phthalates ban without vacatur based on procedural errors, while rejecting substantive challenges to the rule. *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368 (5th Cir. 2021).

and vegetables, and other products. Hauser Decl. ¶ 17; Zota Decl. ¶ 19; Declaration of Michael Belliveau ¶¶ 9–10. Phthalates have been detected in foods certified as organic. Belliveau Decl. ¶¶ 10, 13.

As a result, human exposure to phthalates is effectively ubiquitous. Hauser Decl. ¶ 13; Zota Decl. ¶¶ 3, 30. Biomonitoring studies, which measure specific chemicals and their breakdown products in human blood or urine, have demonstrated that nearly 100% of people in the United States—including children—have measurable levels of phthalates in their body. Hauser Decl. ¶ 13.

At the same time, certain populations are exposed to higher levels of phthalates than the general population and are more susceptible to harm from this exposure. Zota Decl. ¶¶ 23–29, 32; Hauser Decl. ¶¶ 26, 34–36. For example, Black and Latina women of reproductive age experience disproportionately high phthalate exposure and are more likely to suffer from associated health harms. Zota Decl. ¶ 23; *see also* Hauser Decl. ¶ 34. In addition, children, infants, and fetuses experience higher levels of phthalate exposure than the general population and are more susceptible to irreversible harm from these exposures during the critical developmental periods *in utero* and in early childhood. Zota Decl. ¶¶ 5, 25, 29, 31–32; Hauser Decl. ¶¶ 24–30.

Due to the prevalence of phthalates in food packaging and processing materials, and phthalates' tendency to leach out of these materials into food and

drinks, diet is the primary source of exposure to most phthalates in the general population. Zota Decl. ¶¶ 3, 16; Hauser Decl. ¶¶ 17, 31. Yet, because of the widespread use of phthalates in food packaging and processing materials—and the resulting contamination of countless food products—it is virtually impossible for individual consumers to avoid harmful levels of exposure through their food choices. Zota Decl. ¶¶ 19, 30; Hauser Decl. ¶ 17. This is particularly true for individuals who frequently eat cafeteria food, fast food, and other processed foods, which often is driven by their income or where they live or work. *See* Zota Decl. ¶ 24. Further, the presence of phthalates in food and drinks is not disclosed to consumers on labels. As a result, it is not feasible for consumers to make informed purchasing decisions that would protect them from phthalate exposure through their diet. Hauser Decl. ¶ 17.

II. FDA HAS A DUTY TO ENSURE THE SAFETY OF FOOD ADDITIVES

The Food Act's primary purpose is "to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014) (citations omitted). The statute directs FDA to "protect the public health by ensuring that . . . foods are safe." 21 U.S.C. § 393(b)(2)(A). As a core part of this mandate, FDA has a duty to ensure the safety of all food additives, *id.* §§ 342(a)(2)(c), 348, which include substances added directly to food and substances used in food packaging or processing materials that "may reasonably be

expected" to migrate into food, *id.* § 321(s); *see also id.* § 348(a)(3); 21 C.F.R. § 170.3(e)(1).

All new food additives, and new uses of existing additives, are presumed to be unsafe and their use prohibited unless their manufacturer provides adequate evidence to FDA to establish "that the proposed use of the food additive . . . *will be safe*." 21 U.S.C. § 348(a), (c)(3)(A) (emphasis added). To satisfy this standard, the evidence before FDA must be sufficient to support "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use," 21 C.F.R. § 170.3(i), meaning it will not "injure or otherwise damage the health of individuals consuming the additive," Final Rule, Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 61 Fed. Reg. 3,118, 3,119 (Jan. 30, 1996).

In determining whether a substance satisfies this safety standard, FDA must consider (1) "the probable consumption of the additive and of any substance formed in or on food because of the use of the additive"; (2) "the cumulative effect" of the additive in the diet, "taking into account any chemically or pharmacologically related substance or substances in [the] diet"; and (3) scientifically accepted "safety factors" to provide a margin of safety for human health where FDA is relying on safety studies conducted in animals. 21 U.S.C. § 348(c)(5).

Any person may file a food additive petition requesting that FDA issue, amend, or repeal a food additive authorization. *Id.* § 348(b)(1), (i); 21 C.F.R. § 171.1; *Nat. Res. Def. Council*, 645 F.3d at 402–03. Thus, food additive petitions are a vehicle both for manufacturers to seek FDA approval for new additives or additive uses and for the public to seek modification or revocation of existing food additive authorizations.[3]

The Food Act requires FDA to issue a final order granting or denying a food additive petition within ninety days of accepting the petition for filing, though FDA may extend this deadline by up to ninety days if necessary by providing notice to the petitioner before the default ninety-day period expires. *See* 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100(a), (c). The statute does not authorize FDA to delay final action on food additive petitions beyond 180 days under any circumstances. *See* 21 U.S.C. § 348(c)(2) (requiring that FDA's decision granting or denying petition "shall be issued . . . not more than one hundred and eighty days after the date of filing of the petition").

[3] In certain circumstances not at issue here, a manufacturer of a substance that is expected to migrate from food packaging or processing materials into food (referred to by FDA as a "food contact substance," 21 U.S.C. § 348(h)(6); 21 C.F.R. § 170.3(e)(1), (3)), may alternatively submit proof of the substance's safety to FDA through a food contact substance notification that satisfies procedural requirements in the Food Act and implementing regulations, 21 U.S.C. § 348(h); *see* 21 C.F.R. §§ 170.100–170.106.

III. FDA'S DECISION ON THE 2016 PETITION IS YEARS OVERDUE

FDA regulations currently authorize uses of twenty-eight phthalates in food packaging and processing materials from which the chemicals are expected to migrate into food, including in plastic and paperboard food packaging and in adhesives, inks, lubricants, equipment sanitizers, plastic and rubber equipment components, and other food processing materials.[4]

In light of the growing body of evidence linking these chemicals to serious and irreversible harms to human health, on March 18, 2016, the Food Safety Groups submitted a food additive petition to FDA requesting that FDA (1) repeal its existing regulations authorizing uses of phthalates in food packaging and processing materials, and (2) promulgate new regulations prohibiting food contact uses of the eight phthalates that the Consumer Product Safety Commission's expert panel on phthalates determined are unsafe or likely to cause developmental harm. Petition at 1, 68.[5]

[4] *See* 21 C.F.R. §§ 175.105, 175.300, 175.320, 175.380, 175.390, 176.170, 176.180, 176.210, 176.300, 177.1010, 177.1200, 177.1210, 177.1400, 177.1460, 177.1590, 177.2420, 177.2600, 178.3740, 178.3910, 181.27.

[5] The Food Safety Groups' original Petition addressed thirty chemicals, but they subsequently narrowed its scope to cover twenty-eight phthalates. *See* Letter from Breast Cancer Fund et al., to Dr. Kelly Randolph, FDA, Re: Food Additive Petition No. 6B4815 Regarding Ortho-phthalates/Preliminary Response to Sept. 1, 2016 Request, at 2 (Oct. 8, 2016) (Neltner Decl., Ex. 7).

The Petition presented evidence that the FDA-approved phthalates are "chemically or pharmacologically related," 21 U.S.C. § 348(c)(5)(B), such that FDA must consider their cumulative health effects when evaluating their safety, Petition at 3–8. Next, the Petition argued that current levels of dietary exposure to phthalates put people at risk of serious health harms. *Id.* at 11–15.

The Petition also presented significant new evidence documenting the dangers of phthalate exposure that FDA had not considered when it approved the use of phthalates in food packaging and processing materials. This evidence included the 2014 report from the Consumer Product Safety Commission's expert panel on phthalates, which recommended banning eight phthalates addressed in the Petition from toys and childcare articles based on their harmful health effects. *See id.* at 1, 5, 8–12, 31, 34–57.

The Petition also explained that FDA lacks safety data for most of the other phthalates the agency has approved, including data evaluating the potential for reproductive, developmental, and endocrine damage from seventeen of the approved phthalates. *See id.* at 6. Based on the substantial evidence affirmatively demonstrating the health hazards of numerous FDA-approved phthalates, the lack of safety data for many of the other approved phthalates that have similar properties, and the evidence that current levels of dietary exposure to phthalates endanger people's health, the Petition argued that FDA can no longer conclude

with reasonable certainty that the approved phthalates are safe for use in the food additive applications FDA has authorized. *Id.* at 2–3, 15, 17. Therefore, the Petition requested that FDA repeal those authorizations and promulgate new regulations banning future food contact uses of the eight phthalates that the Consumer Product Safety Commission's expert panel determined to be unsafe or likely to cause developmental harm. *Id.* at 1.

On April 12, 2016, FDA notified the Food Safety Groups that it was accepting for filing the portion of the Petition asking FDA to revoke its existing regulations authorizing food additive uses of phthalates. Letter from Dr. Francis Lin, FDA, to Tom Neltner, Env't Def. Fund ("EDF"), Re: Food Additive Petition (FAP) No. 6B4815 (Apr. 12, 2016) (Neltner Decl., Ex. 2).[6] On September 1, 2016,

[6] FDA did not accept for filing the portions of the Petition asking FDA to (1) promulgate new regulations banning food contact uses of the eight phthalates banned from use in toys and childcare articles, and (2) revoke FDA's authorizations for five phthalates that are on FDA's list of "prior-sanctioned substances," *see* 21 C.F.R. § 181.27, which includes substances FDA approved for use in food or food packaging before September 6, 1958, *see* 21 U.S.C. § 321(s)(4) (excluding such substances from the definition of "food additives"). Neltner Decl., Ex. 2 at 1. Instead, FDA asserted that the Food Safety Groups had to resubmit these requests in a separate "citizen petition," which is subject to different procedural requirements than a food additive petition. *Id.*; *see* 21 C.F.R. § 10.30 (citizen petition regulations). The Food Safety Groups disputed FDA's position but protectively resubmitted these two requests in a citizen petition on April 19, 2016. Breast Cancer Fund et al., *Citizen Petition Requesting That FDA Remove its Prior Sanction of Five Ortho-Phthalates and Ban Eight Ortho-Phthalates* (Apr. 19, 2016) (Neltner Decl., Ex. 3). The citizen petition—which FDA has also failed to act on in the intervening five-plus years—is not at issue in this proceeding.

FDA sent the Food Safety Groups a deficiency notice stating that FDA required substantial additional information to continue reviewing the Petition and could place the petition in abeyance if FDA did not receive the requested information within forty-five days. Letter from Dr. Kelly Randolph, FDA, to Tom Neltner, EDF, Re: Food Additive Petition (FAP) No. 6B4815 (Sept. 1, 2016) (Neltner Decl., Ex. 6). Alternatively, FDA advised that if the Food Safety Groups "consider[ed] the deficiencies discussed in [FDA's] letter to be of no significance, [the Groups] should provide an explanation of [their] position and request that the agency render a final decision without this information." *Id.* at 5.

The Food Safety Groups endeavored to provide the information FDA requested. They provided a preliminary response to FDA on October 8, 2016, and asked for a meeting to discuss FDA's requests, which occurred on October 31, 2016. *See* Neltner Decl. ¶¶ 13–14, 16 & Ex. 7; Mem. from Dr. Kelly Randolph, FDA, on the Discussion on Petitioners [sic] Preliminary Responses to FDA's September 1, 2016 Deficiency Letter Regarding Food Additive Petition (FAP) 6B4815 (Dec. 8, 2016) (Neltner Decl., Ex. 10). Following that meeting, the Food Safety Groups prepared a supplemental response to FDA's information requests, which they sent to FDA on August 24, 2017. Letter from Breast Cancer Prevention Partners et al., to Dr. Kelly Randolph, FDA, Re: Food Additive Petition No. 6B4815 Regarding Ortho-Phthalates/Response to Sept. 1, 2016 Request (Aug.

24, 2017) (Neltner Decl., Ex. 11). That response included seventy-one pages of analysis, supported by more than 200 scientific articles. *See id.*

More than six months later, FDA acknowledged receipt of the Food Safety Groups' August 2017 response, which the agency characterized as only a "partial" response, and requested still more evidence and analysis. Letter from Dr. Kelly Randolph, FDA, to Tom Neltner, EDF, Re: Food Additive Petition (FAP) No. 6B4815 (Mar. 5, 2018) (Neltner Decl., Ex. 12). At the same time, FDA repeated its direction that the Food Safety Groups should advise FDA if they considered the alleged deficiencies "to be of no significance . . . and request that the agency render a final decision" on the Petition without additional information, which "in all likelihood," would result in FDA's "proceed[ing] to deny the petition." *Id.* at 13.

One week later, on March 12, 2018, the Food Safety Groups sent FDA a letter advising FDA that they considered the remaining alleged deficiencies insignificant to FDA's evaluation of the Petition and requested that FDA "issue a final decision based on the information presently before you." Letter from Tom Neltner, EDF, to Dr. Kelly Randolph, FDA, Re: Food Additive Petition (FAP) No. 6B4815 Regarding 28 Ortho-Phthalates (Mar. 12, 2018) (Neltner Decl., Ex. 13). This letter did not include any new evidence supporting the Petition; to the

contrary, it requested a prompt decision based on the information already submitted. *See id.*

FDA responded by letter dated March 26, 2018, advising the Food Safety Groups that FDA had taken the Petition out of abeyance. Letter from Dr. Kelly Randolph, FDA, to Tom Neltner, EDF, Re: Food Additive Petition (FAP) No. 6B4815 (Mar. 26, 2018) (Neltner Decl., Ex. 14). However, FDA claimed that "because of the nature of the information" in the Food Safety Groups' March 12, 2018, letter requesting a final decision, the Groups had made "a substantive amendment" to the Petition that justified FDA's assigning the Petition a new filing date of March 12, 2018. *Id*.

On March 30, 2018, the Food Safety Groups responded by letter disputing FDA's characterization of their request for a final decision as a "substantive amendment" to the Petition that justified a new filing date. Letter from Carrie Apfel, Earthjustice, & Tom Neltner, EDF, to Dr. Kelly Randolph, FDA, Re: Food Additive Petition (FAP) No. 6B4815 Regarding 28 Ortho-Phthalates (Mar. 30, 2018) (Neltner Decl., Ex. 15). Ultimately, FDA failed to take final action on the Petition within 180 days of even the newly assigned March 12, 2018, filing date.

The Food Safety Groups sent FDA letters on November 9, 2018, and January 21, 2020, reiterating their request for a final decision on the Petition and reminding FDA that its decision was long overdue pursuant to the Food Act's

deadlines. Letter from Carrie Apfel, Earthjustice, & Tom Neltner, EDF, to Dr. Kelly Randolph, FDA, Re: Food Additive Petition (FAP) No 6B4815 Regarding 28 Ortho-Phthalates (Nov. 9, 2018) (Neltner Decl., Ex. 18); Letter from Carrie Apfel, Earthjustice, & Tom Neltner, EDF, to Dr. Kelly Randolph, FDA, Re: Food Additive Petition (FAP) No. 6B4815 Regarding 28 Ortho-Phthalates (Jan. 21, 2020) (Neltner Decl., Ex. 19.). FDA did not respond.

More than five and a half years after the Food Safety Groups submitted the Petition, and more than three and a half years after FDA's revised filing date, FDA still has not issued an order granting or denying the Petition.

SUMMARY OF ARGUMENT

FDA's failure to act on the Petition more than five and a half years after its submission and more than three and a half years after FDA's revised filing date violates the Food Act, 21 U.S.C. § 348(c)(2), FDA's regulations, 21 C.F.R. § 171.100, and the Administrative Procedure Act, 5 U.S.C. § 706(1), and warrants mandamus relief from this Court.

First, this Court has jurisdiction to issue a writ of mandamus because (1) Petitioners have "a clear and indisputable right to relief," (2) FDA "is violating a clear duty to act," and (3) "no adequate alternative remedy exists." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (citation omitted). More than three and a half years have passed since FDA agreed to take the Petition out of

abeyance and conclude its decision-making process. Accordingly, FDA is violating its clear duty under the Food Act to make a final decision within no more than 180 days. 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100. And Petitioners have no alternative remedy, as FDA has ignored multiple requests for a final decision.

Second, the equities strongly favor mandamus relief. FDA's years-long delay flouts Congress's command for FDA to decide food additive petitions within no more than 180 days. 21 U.S.C. § 348(c)(2). And as attested by leading experts on the health effects of phthalate exposure, FDA's delay has caused and continues to cause serious harm to human health, in direct contravention of the governing statute's health-protective purpose.

STANDING

Petitioners have standing to sue on behalf of their members and supporters because (1) "the interests [they] seek[] to protect are germane to the organization[s'] purpose[s]," (2) "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit," and (3) Petitioners' members and supporters "would otherwise have standing to sue in their own right." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977); *see Flyers Rights Educ. Fund v. U.S. Dep't of Transp.*, 957 F.3d 1359, 1361–62 (D.C. Cir. 2020) (affirming that an organization that is not "a traditional membership organization" may sue on behalf of "individuals associated with the

organization who are the 'functional equivalent' of members"). "When more than one association brings suit," the Court "need only find one party with standing to satisfy the standing requirement." *Air All. Hous. v. EPA*, 906 F.3d 1049, 1058 (D.C. Cir. 2018) (quotation and alteration omitted).

Petitioners satisfy this standard. First, this case seeks to advance one of Petitioners' core purposes of protecting human health from toxic chemicals such as phthalates. *See* Neltner Decl. ¶¶ 3–6; Declaration of Tracy Gregoire ¶¶ 2–4; Declaration of Jaydee Hanson ¶¶ 3–6; Declaration of Susan L. Chiang ¶¶ 2, 5–7, 14–15; Declaration of Peter Lurie ¶¶ 2, 9–12; Declaration of Lisette van Vliet ¶¶ 2–5, 7–10; Belliveau Decl. ¶¶ 1, 4–6; Declaration of Margaret Yellow Wolf Tarrant ¶¶ 2–4, 8–10.

Second, this lawsuit does not require the participation of individual members, as it "turns entirely on whether [FDA] complied with its statutory obligations" to make a timely decision on the Petition and seeks to compel that overdue agency action. *Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 597 (D.C. Cir. 2015).

Third, Petitioners' members and supporters would have standing to sue on their own behalf because they suffer "injury in fact" that is fairly traceable to FDA's inaction and likely to be redressed by a favorable decision. *Friends of the Earth v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000). Because

Petitioners assert a procedural injury from FDA's violation of the statutory deadline to act on the Petition, "the primary focus of the standing inquiry is not the imminence or redressability of the injury to the [petitioner], but whether a [petitioner] who has suffered personal and particularized injury has sued a [respondent] who has caused that injury." *City of Dania Beach v. FAA*, 485 F.3d 1181, 1185 (D.C. Cir. 2007) (quoting *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996) (en banc)); *see also WildEarth Guardians v. Jewell*, 738 F.3d 298, 305 (D.C. Cir. 2013) (affirming that causation and redressability requirements are relaxed in procedural injury cases).

Here, Petitioners' members and supporters have been and continue to be injured by FDA's failure to act on the Petition within the Food Act's 180-day deadline because the agency's delay has subjected them and their children to years of exposure to harmful phthalates in their food. *See* Hauser Decl. ¶¶ 2–3, 17–37 (describing documented risks of serious and irreversible health harms from dietary exposure to phthalates); Zota Decl. ¶¶ 4–7, 26–29, 31–32 (describing these risks and disproportionate harm to specific populations); Belliveau Decl. ¶¶ 9–11, 13 (describing evidence of phthalate contamination of food products); *City of Dania Beach*, 485 F.3d at 1185 (affirming that petitioners establish cognizable procedural injury by showing that agency's violation of procedural requirement "will cause a

distinct risk to a particularized interest" of petitioners (quoting *Fla. Audubon Soc'y*, 94 F.3d at 664)).

Petitioners' members and supporters and their children eat numerous food products in which phthalate contamination has been detected, including milk and other dairy products, meat, cooking oils, spices, and various processed and packaged foods. *See, e.g.*, Yellow Wolf Tarrant Decl. ¶¶ 11, 14–19; Declaration of Alexandra Moulton ¶¶ 6–8; Declaration of Jean Bissell ¶¶ 8–10. Petitioners' members and their children dine at restaurants, including fast food restaurants, which is associated with elevated exposure to phthalates. *See, e.g.*, Yellow Wolf Tarrant Decl. ¶ 14; Bissell Decl. ¶ 8; Declaration of Laura Seaton ¶ 7; Declaration of Paul Ames ¶ 6.

Petitioners' members include parents of young children who are more susceptible to harm from phthalate exposure, including children who have experienced health harms linked to phthalates. *See* Seaton Decl. ¶¶ 1, 4–5; Moulton Decl. ¶¶ 1, 5. Petitioners' members also depend upon school cafeteria meals to feed their children, which are associated with heightened phthalate exposure in this vulnerable age group. *See* Seaton Decl. ¶ 9; Yellow Wolf Tarrant Decl. ¶ 15; Moulton Decl. ¶ 7.

In addition to the documented risks of harm to the health of these individuals and their children, Petitioners' members and supporters experience stress and

anxiety knowing that phthalates are in the food they eat and feed to their children, *see, e.g.*, Moulton Decl. ¶ 10; Bissell Decl. ¶¶ 5–6, 8, 11; Declaration of Rachel Doughty ¶ 14, and they spend money and time trying to avoid or reduce their exposure, *see* Bissell Decl. ¶ 7; Seaton Decl. ¶ 10; Doughty Decl. ¶ 11; Ames Decl. ¶ 9.

This exposure among Petitioners' members and supporters and their children to dangerous contaminants in their food, and the need to change their behavior and invest money trying to reduce this exposure, satisfies the injury-in-fact requirement. *See, e.g.*, *Sierra Club v. EPA*, 755 F.3d 968, 974 (D.C. Cir. 2014) (holding organizations' members demonstrated injury-in-fact from agency rule allowing combustion of hazardous materials at refineries by attesting that members lived near refineries capable of processing the materials and "explain[ing] those individuals' particularized fears of serious health and environmental consequences from the gasification process, and their individual behavioral changes prompted by the toxic exposure that Petitioners aver the regulatory exemption will cause" (citation omitted)).

Despite their efforts, however, Petitioners' members and supporters and their children continue to suffer dangerous exposure to phthalates in their diet because that exposure is not possible to avoid through individual choices. Zota Decl. ¶¶ 19, 30; Hauser Decl. ¶ 17. This is so because of the widespread use of phthalates in

food packaging and processing materials pursuant to the FDA authorizations Petitioners seek to revoke and because the presence of phthalates in food is not disclosed on labels. Hauser Decl. ¶ 17; Zota Decl. ¶ 19.

Accordingly, Petitioners' injuries are caused by FDA's failure to act on the Petition and those injuries are redressable by this Court. "A [petitioner] asserting procedural injury never has to prove that if he had received the procedure the substantive result would have been altered." *City of Dania Beach*, 485 F.3d at 1186 (quotation omitted). Instead, they need only "demonstrate a causal connection between the agency action and the alleged injury." *Id.* (citation omitted). If FDA takes final action on the Petition as the Food Act requires, it would reduce or eliminate the phthalate contamination in food Petitioners' members and supporters eat and feed to their children, or FDA would issue an order denying the Petition that Petitioners could challenge through an administrative appeal and/or judicial review. Relief from this Court would redress Petitioners' injuries by compelling FDA at last to issue the decision on the 2016 Petition that the Food Act demands. And that relief is necessary to redress Petitioners' injuries given FDA's persistent disregard of its statutory duty to act. *See Fla. Audubon Soc'y*, 94 F.3d at 668 (noting procedural injuries are "easily redressable, as a court may order the agency to undertake the procedure" it has failed to follow); *In re Idaho Conservation League*, 811 F.3d 502, 513 (D.C. Cir.

2016) (affirming that parties alleging procedural injury establish redressability by showing that the procedural compliance they seek to compel is "connected to the substantive result" they ultimately seek (quotation and citation omitted)). Petitioners have standing.

ARGUMENT

FDA's failure to act on the Petition more than five and a half years after its submission and more than three and a half years after FDA's revised filing date violates the Food Act, 21 U.S.C. § 348(c)(2), FDA's regulations, 21 C.F.R. § 171.100, and the Administrative Procedure Act, 5 U.S.C. § 706(1), and warrants mandamus relief from this Court.

This Court's analysis of mandamus petitions proceeds in two phases. First, the Court considers whether Petitioners have established this Court's jurisdiction to issue the writ by demonstrating "a clear and indisputable right to relief" arising from an agency's violation of "a clear duty to act" that leaves Petitioners without any "adequate alternative remedy." *Am. Hosp. Ass'n*, 812 F.3d at 189 (citing *United States v. Monzel*, 641 F.3d 528, 534 (D.C. Cir. 2011)). If these requirements are met, the Court then considers whether "compelling equitable grounds" justify mandamus relief. *Id.* (quoting *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005)). In cases like this where the governing statute "imposes a deadline or other clear duty to act," the Court's analysis focuses

on "the equitable question of whether mandamus *should* issue, rather than the jurisdictional question of whether it *could*." *Id.* at 190.

"Mandamus is an extraordinary remedy reserved for extraordinary circumstances." *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004) (citing *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 549 (D.C. Cir. 1999)). "An administrative agency's unreasonable delay presents such a circumstance because it signals the 'breakdown of regulatory processes.'" *Id.* (quoting *Cutler v. Hayes*, 818 F.2d 879, 897 n.156 (D.C. Cir. 1987)).

Here, FDA's failure to act on the Petition indisputably violates the deadline established in the Food Act, and FDA's persistent refusal to act despite Petitioners' repeated requests has left Petitioners without recourse before the agency. Moreover, FDA's years-long delay in acting on Petitioners' request to revoke federal authorization for food additive uses of phthalates endangers human health—including the health of developing fetuses, infants, and children, who are threatened with irreversible damage to their neurological and reproductive development from exposure to phthalates in food. FDA's inaction also perpetrates an environmental injustice by disproportionately harming Black, Latino, and low-wealth people who experience heightened exposure to phthalates and greater susceptibility to harm from that exposure. These circumstances justify mandamus relief requiring FDA to act on the Petition within sixty days.

I. THIS COURT HAS JURISDICTION TO ISSUE A WRIT OF MANDAMUS

This Court has jurisdiction to grant mandamus relief because (1) Petitioners have "a clear and indisputable right to relief," (2) FDA "is violating a clear duty to act," and (3) "no adequate alternative remedy exists." *Am. Hosp. Ass'n*, 812 F.3d at 189 (citation omitted).

Petitioners have a clear right to relief from FDA's failure to act on the 2016 Petition. The APA dictates that a "reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), and an agency's "failure to promulgate a rule or take some decision by a statutory deadline" constitutes a failure to act within the meaning of that statute, *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004); *accord Am. Hosp. Ass'n*, 812 F.3d at 191. FDA is violating a clear duty, established in the Food Act, to take timely action on the Petition.

Congress directed that FDA "shall" issue an order granting or denying a food additive petition within no more than 180 days. 21 U.S.C. § 348(c)(2); *see also* 21 C.F.R. § 171.100(a), (c). This is a mandatory deadline; "FDA must grant or deny a food additive petition in accordance with the statutory timeline in section 409(c)(2) of the Act." *Nat. Res. Def. Council*, 645 F.3d at 403 (citing 21 C.F.R. § 171.100); *see also In re Barr Laboratories*, 930 F.2d 72, 74 (D.C. Cir. 1991) (holding that provision in the same statute directing that FDA "shall" approve or

reject generic drug application within 180 days establishes a mandatory deadline (quotation omitted)); *United Mine Workers*, 190 F.3d at 550 (affirming that statutory directive that agency "*shall*" make a decision within specified time period indicates a mandatory deadline (quotation omitted)).

FDA is indisputably violating this requirement. FDA accepted the Petition for filing on April 12, 2016. Neltner Decl. ¶ 8. Even accepting for the sake of argument that FDA properly revised the filing date to March 12, 2018, which Petitioners dispute, FDA's decision was due no more than 180 days later, *i.e.*, September 8, 2018. Yet more than three years after that deadline, FDA still has not acted.

Petitioners have no alternative remedy to compel FDA's long overdue action on the Petition. Indeed, Petitioners have formally requested an immediate final decision on three occasions, Neltner Decl., Exs. 13, 18, 19, yet FDA persists in its refusal to act. Contrary to its clear statutory duty to grant or deny the Petition within 180 days, FDA has engaged in a "marathon round of administrative keep-away" that has persisted for years and requires judicial intervention to end. *Am. Rivers*, 372 F.3d at 420. This Court has jurisdiction to issue the writ.

II. THE EQUITIES FAVOR MANDAMUS RELIEF FROM FDA'S YEARS-LONG DELAY, WHICH ENDANGERS HUMAN HEALTH

This Court also has a compelling equitable basis to grant mandamus relief. *See Am. Hosp. Ass'n*, 812 F.3d at 190 (stating that where governing statute

"imposes a deadline," the Court's analysis focuses on "the equitable question of whether mandamus *should* issue, rather than the jurisdictional question of whether it *could*"). Where, as here, parties seek mandamus relief to compel overdue agency action, the Court's equitable analysis is guided by the so-called "*TRAC* factors," *id.* at 189, namely:

> (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Id. (quoting *TRAC*, 750 F.2d at 80). These factors "function not as a hard and fast set of required elements, but rather as useful guidance as to whether a delay is 'so egregious as to warrant mandamus.'" *Id.* (quoting *TRAC*, 750 F.2d at 79).

Here, as set forth in the second *TRAC* factor, Congress's deadline requiring FDA action on the Petition within no more than 180 days "supplies content for item one's 'rule of reason.'" *Barr Laboratories*, 930 F.2d at 75. Whether one measures FDA's violation of this deadline from the date it accepted the Petition for filing—more than 2,000 days ago—or the new filing date it assigned over Petitioners' objection—more than 1,300 days ago—this factor strongly favors

relief. *See Am. Hosp. Ass'n*, 812 F.3d at 193 (affirming that "[f]ederal agencies must obey the law," including "statutory deadlines").

While there is "no *per se* rule as to how long is too long to wait for agency action," even absent a statutory deadline this Court has held that "a reasonable time for agency action is typically counted in weeks or months, not years." *Am. Rivers*, 372 F.3d at 419 (quotation and citation omitted) (concluding, despite absence of statutory or regulatory deadline governing agency's decision on Endangered Species Act petition, that agency's "six-year-plus delay is nothing less than egregious"). Here, FDA's years-long inaction flouts Congress's command that FDA decide food additive petitions within no more than 180 days. 21 U.S.C. § 348(c)(2). This "transparent violation[] of a clear duty to act" favors relief. *Am. Rivers*, 372 F.3d at 418 (quoting *In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000)).

The harmful effect of FDA's delay on human health also strongly favors relief. *See Am. Hosp. Ass'n*, 812 F.3d at 193. The third and fifth *TRAC* factors direct the Court "to be particularly wary of delay when human health and welfare are at stake." *United Mine Workers*, 190 F.3d at 552, 552 n.6. "Delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake. This is particularly true when the very purpose of the governing Act is to protect those lives." *Pub. Citizen Health Rsch. Grp. v.*

Auchter, 702 F.2d 1150, 1157–58 (D.C. Cir. 1983) (citations and footnote omitted).

The Food Act's purpose is, in relevant part, to protect human health by prohibiting the use of any food additive that is not proven to be safe. *See* 21 U.S.C. §§ 342, 348 (prohibiting use of unsafe food additives). The Petition seeks to advance that purpose by securing revocation of FDA's authorizations for food additive uses of phthalates based on substantial scientific evidence that they are unsafe. The Petition cites evidence linking FDA-approved phthalates to serious adverse health effects, including disruption of the endocrine system, malformation of the reproductive organs, damage to the liver and kidneys, and harm to the developing brain. *See* Petition at 31–53. Indeed, as the Petition references, the Consumer Product Safety Commission's expert panel on phthalates determined in 2014 that eight of these chemicals are too dangerous to use in toys and childcare articles. *See id.* at 1, 5, 5 n.14. The Petition explains that other FDA-approved phthalates share a similar structure and pathway of metabolism in the human body, which undermines the continued validity of FDA's conclusions that these substances are safe for use in food packaging and processing materials. *See id.* at 2–8. The Petition explains that the chemicals' FDA-approved uses lead to phthalate contamination of the food supply, *id.* at 14–15, 27–29, which is the primary pathway for human exposure to these toxic chemicals, Zota Decl. ¶¶ 3, 16;

Hauser Decl. ¶ 17. The Petition cites evidence that high-risk groups such as pregnant women and children are exposed to unsafe levels of phthalates through their diet. Petition at 7–8, 14–16.

Evidence that dietary exposure to phthalates endangers human health has only mounted during the years FDA has sat on the Petition. At this point, "[t]he link between phthalate exposures and adult male reproductive harms"—including damage to sperm quality that can in turn harm a developing fetus or cause infertility—"is well established." Hauser Decl. ¶ 20. There is also a growing body of evidence linking phthalate exposure *in utero* and in early childhood to neurodevelopmental harm that can result in life-altering behavioral disorders and reduced IQ. *Id*. ¶ 30; Zota Decl. ¶ 29. And recent studies have strengthened the link between phthalate exposure and difficulty conceiving a pregnancy, adverse pregnancy outcomes, and other reproductive health harms. Hauser Decl. ¶ 22. Evidence documenting the unique importance of food as a source of phthalate exposure also has grown, as well as the evidence that Black, Latino, and low-wealth people are disproportionately harmed by dietary exposure to phthalates. *See* Zota Decl. ¶¶ 23–29; Hauser Decl. ¶ 34.

This evidence strongly favors mandamus relief. *See Am. Hosp. Ass'n*, 812 F.3d at 193 (holding that evidence that agency's delay is "having a real impact on 'human health and welfare'" is a "significant" factor favoring mandamus relief

(quoting *TRAC*, 750 F.2d at 80)). Preeminent experts in human exposure to phthalates and the associated health risks attest that "[f]or every year that FDA fails to act on [the Petition], more people continue to be exposed to levels of phthalates in their food that are damaging to their health." Zota Decl. ¶ 31; *see also* Hauser Decl. ¶¶ 3, 37. Of particular concern is the fact that children, infants, and developing fetuses have been exposed to phthalates through dietary sources for years due to FDA's inaction and continue to be exposed while FDA's delay persists, as "[t]he effects of these early-life exposures on health and development can alter a person's entire life trajectory." Zota Decl. ¶ 31; *see also* Hauser Decl. ¶ 37. In sum, FDA's years-long delay has caused "unnecessary and avoidable harm to the health of children, women, and men in the United States." Hauser Decl. ¶ 3.

None of the other *TRAC* factors weighs against Petitioners' request for relief. The fourth *TRAC* factor instructs the Court to consider the effect of expediting delayed action on agency activities of a higher or competing priority. *TRAC,* 750 F.2d at 80. Petitioners are not aware of any food additive petitions of a higher or competing priority that have been pending for a similar length of time, and FDA has not identified any. And even if FDA's Office of Food Additive Safety, which is responsible for food additive petitions, has other important priorities relevant to protecting public health, that does not justify withholding

relief. "However many priorities the agency may have, and however modest its personnel and budgetary resources may be, there is a limit to how long it may use these justifications to excuse inaction in the face of the congressional command to act" by a date certain. *United Mine Workers*, 190 F.3d at 554.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request a writ of mandamus directing FDA to issue a final decision granting or denying the Petition within sixty days.

Respectfully submitted this 7th day of December, 2021.

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CERTIFICATE OF COMPLIANCE

This Petition for Writ of Mandamus complies with the type-volume limitation of Fed. R. App. P. 21(d)(1) because it contains 7,781 words, excluding those parts of the petition exempted by Fed. R. App. P. 32(f).

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.

Dated: December 7, 2021

/s/Katherine K. O'Brien
Katherine K. O'Brien

CERTIFICATE OF PARTIES AND AMICI CURIAE

Pursuant to Circuit Rules 21(d) and 28(a)(1), Petitioners state as follows:

(A) Parties, Intervenors and Amici:

The Petitioners in this case are Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend Our Health, and Alaska Community Action on Toxics. The Respondents are the U.S. Food and Drug Administration and Dr. Janet Woodcock, in her official capacity as Acting Commissioner of the U.S. Food and Drug Administration.

Dated: December 7, 2021

/s/Katherine K. O'Brien
Katherine K. O'Brien

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a) and Circuit Rule 26.1(a), Petitioners Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend Our Health, and Alaska Community Action on Toxics state that they are nonprofit organizations, have no parent corporations, and no publicly held corporation owns 10% or more of their stock.

Dated: December 7, 2021

/s/Katherine K. O'Brien
Katherine K. O'Brien

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of December, 2021, I caused copies of the foregoing Petition for Writ of Mandamus, Certificate of Parties and Amici Curiae, and Corporate Disclosure Statement, and the attached Petitioners' Addendum of Declarations to be served via Federal Express on the entities or persons at the addresses listed below:

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Dated: December 7, 2021

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